

POLICY ISSUE INFORMATION

July 12, 2002

SECY-02-0131

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: UPDATE OF THE RISK-INFORMED REGULATION IMPLEMENTATION PLAN

PURPOSE:

To present the Commission with an updated and revised version of the Risk-Informed Regulation Implementation Plan (RIRIP) and to respond to the staff requirements memorandum (SRM) dated February 8, 2002, regarding the “convergence” of risk-informed activities pertaining to reactor safety. This paper also provides a summary of public PRA Steering Committee meetings held since December 2001.

SUMMARY:

The RIRIP discusses the Agency’s actions to risk-inform its regulatory activities and specifically describes each of the activities identified as supporting the goals and objectives of the Agency’s Strategic Plan and the Probabilistic Risk Analysis Policy Statement.

The RIRIP is organized into two parts. Part 1 provides a general discussion of the document's relationship to the PRA Policy Statement and the Strategic Plan. It also discusses deterministic and other elements for consideration in the process of risk-informing and provides guidance for selecting appropriate “candidates” for risk-informing. Part 2 describes the staff’s ongoing risk-informed regulation activities in the reactor safety arena and the waste safety and materials safety arenas.

The Agency’s accomplishments in risk-informing its regulatory activities since December 2001 are described in Attachment 1. Key risk-informing activities to be conducted at the Agency over the next 6 months are described in the paragraphs below.

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Reactor Safety Arena

1. Option 2 (Special Treatment Requirements): The staff is continuing to work on the statement of considerations and other parts of a proposed rule package. Draft Revision C of the industry guidance document, NEI 00-04, was submitted to the NRC in a letter dated June 28, 2002. The staff plans to complete a draft regulatory guide endorsing this document (with clarification if needed) as part of the proposed rule package. The staff will meet with ACRS in September to discuss the proposed rule and guidance. The current schedule is to forward the proposed rule to the Commission in September 2002.
2. Option 3 (Risk-Informing Part 50)
 - ▶ Hydrogen Control Requirements (10 CFR 50.44): On June 27, 2002, the Commission approved the proposed rulemaking package. The staff is in the process of publishing the proposed rule in the *Federal Register*.
 - ▶ ECCS Acceptance Criteria (10 CFR 50.46): The staff has recommended that separate rulemakings be pursued for proposed changes to ECCS reliability requirements, ECCS acceptance criteria, and ECCS evaluation model requirements. An initial draft report on the approach for modifying the ECCS reliability requirements was completed in May 2002. The final version of this report will be completed in July 2002, as will as reports on the technical bases to support rulemaking for the proposed changes to the ECCS acceptance criteria and evaluation model requirements.
1. In December 2001, the staff posted draft language for a proposed risk-informed and performance-based fire protection rule on the NRC rulemaking website for public review and comment. Comments received through the website were considered in preparing the proposed rule language. The staff gave presentations to the Advisory Committee on Reactor Safeguards the week of June 2, 2002, and the Committee to Review Generic Requirements the week of June 9, 2002. A letter supporting the staff's rulemaking effort was issued by the ACRS on June 17, 2002. The proposed rule will be provided to the Commission in July 2002.
2. In response to a Commission SRM of February 8, 2002, the staff is developing a plan for improving coherence among risk-informed activities. The goals of this plan are to develop a common understanding of risk-informed regulatory objectives and to obtain staff and stakeholder buy-in of the objectives. The plan has five elements: (1) define the problem, (2) develop a structured, systematic framework, (3) develop the desired characteristics of an integrated risk-informed regulatory structure, (4) identify and evaluate risk-informed activities, and (5) prioritize and modify activities, as appropriate. Each part of the plan will take advantage of and build on ongoing staff activities. The staff expects to hold several public meetings and workshops during the next few months and to develop a detailed plan by early fall.
3. In April 2002, NRR completed the first phase of the Risk-Informed Environment initiative. The staff and its contractors have evaluated information collected in the focus groups and interviews and identified the following key challenges to creating an improved environment for risk-informed regulation:

- ▶ create a shared vision of “risk-informed” and “integrated decisionmaking”
- ▶ integrate PRA roles and responsibilities more deeply into the organization
- ▶ improve the knowledge and experience levels within the Office
- ▶ improve communication channels among staff and between staff and management
- ▶ correct misconceptions about PRA technology

The detailed results of the first phase will be shared with the staff. In addition, in conjunction with the coherence initiative, the staff will develop a plan identifying ways of meeting the challenges within the broad areas of communication and information, training, and process improvement.

4. The staff continues to work on numerous risk-informed technical specification initiatives. The safety evaluations for Initiative 1, Technical Specification Actions End State Modifications, and Initiative 3, Modification of Mode Restraint Requirements, will be completed within the next 6 months.
5. The staff is continuing its work to develop a regulatory guide and a Standard Review Plan (SRP) chapter to assess PRA adequacy. The staff expects to have completed the regulatory guide and SRP chapter by December 2002, as well as Appendices A (staff position on the ASME PRA standard on internal events) and B (staff position on the NEI PRA review guidance on internal events).
6. The staff is assessing the need for changes to the pressurized thermal shock (PTS) rule (10 CFR 50.61). Over the remainder of 2002, the staff will continue its activities to identify PTS-related accident sequences; integrate the results of supporting analyses to calculate the frequency of vessel failure and core damage; recommend changes to operational limits associated with PTS acceptance criteria; and assess the need for PTS rule changes and provide recommendations.

Waste Safety and Materials Safety Arenas

1. The final rule amending the regulations regarding the medical use of byproduct material (10 CFR Part 35) becomes effective on October 24, 2002 (67 FR 20249). The final rule is one component of the Commission's program for revising its medical use regulatory framework to focus the regulations on high-risk medical procedures and to make its regulations more risk-informed and more performance-based. Prior to the effective date, staff will complete other elements of the program, including the revision of NUREG-1556, Volume 9, “Program-Specific Guidance About Medical Use Licenses,” and the revision of four medical inspection procedures to reflect final rule changes to 10 CFR Part 35. Training will also be conducted for licensing and inspection staff and will be made available to staff in Agreement States.
2. The staff anticipates the issuance of a final rule in September 2002 to amend the regulations governing the disposal of high-level radioactive wastes at Yucca Mountain to define the term “unlikely” in quantitative terms. The term will be defined as a range of numerical values to determine whether a feature, event, or process, or a sequence of events and processes, should be excluded from certain required assessments.

3. As part of the effort to make the fuel cycle oversight program more risk-informed and performance-based, the staff plans to complete the revision of Inspection Manual Chapter 2600, "Fuel Cycle Facility Operational Safety and Safeguards Inspection Program," by October 2002.
4. The staff is currently reviewing and consolidating all decommissioning policy and guidance documents to support the use of efficient and risk-informed approaches by staff and licensees. During the next 6 months, the staff intends to complete the final version of Volume 1 of a three-volume NUREG report documenting the policy and guidance and to release Volumes 2 and 3 for public comment.

BACKGROUND

In a January 2000 memorandum to the Commission, the staff outlined a strategy for implementing risk-informed regulation. The strategy evolved into the initial version of the Risk-Informed Regulation Implementation Plan (RIRIP), which the staff gave to the Commission in March 2000. The Commission reviewed the plan and, after a briefing by the staff in March, directed the staff in April 2000 to include in the next update of the implementation plan an internal communications plan, staff training requirements, and a discussion of internal and external factors that may impede risk-informed regulation. The first complete version of the implementation plan was issued in October 2000.

In an SRM dated January 4, 2001, the Commission requested that the staff provide a more detailed communication plan to better highlight the Agency's goal of improving public confidence, prioritize activities, identify necessary resources and tools, address how performance-based regulatory approaches will be integrated into the process of risk-informing regulations, and identify critical-path activities and those that have cross cutting dimensions.

In response to the SRM, the December 2001 update of the RIRIP, specifically Part 2, included expanded arena chapters that describe the staff's progress in prioritizing the various implementation activities and identifying the necessary resources and tools, critical-path activities, and activities that have cross cutting dimensions. The arena chapters also describe arena-specific activities related to communication with both internal and external stakeholders. This update of the RIRIP includes updates and additions to the activity descriptions. Several new risk-informed activities have been initiated since the December 2001 RIRIP was issued. These include two new reactor safety arena activities and six new activities in the materials safety and waste safety arenas. The new reactor arena activities are (1) a strategy to improve coherence among risk-informed activities in the reactor arena (see discussion below), and (2) the development of a regulatory guide and SRP to assess PRA adequacy for decisionmaking (see Part 2, Chapter 1, Activity RS-EER1-8). The discussion of the first activity responds to the Commission's SRM of February 2002, as discussed below.

There are six new activities in the materials and waste safety arenas: (1) develop a guide for performing risk analyses, (2) develop safety goals for the materials and waste safety arenas, (3) evaluate low-level source material containing low levels of thorium and/or uranium, (4) evaluate byproduct materials exemptions, (5) amend Part 63, and (6) do a cross cutting risk assessment of

spent fuel management. These new activities are discussed in detail in Part 2, Chapter 2, of the plan.

DISCUSSION

Over the past few years, the staff has made significant progress toward risk-informing its regulatory activities. Attachment 1 to this Commission paper summarizes the staff's significant accomplishments since publication of the December 2001 RIRIP. While the staff has made considerable progress, work remains to be done. Using the Probabilistic Risk Assessment (PRA) Policy Statement and the NRC's Strategic Plan as a foundation, the RIRIP describes activities that are planned and underway and the interrelationships among the activities.

Plan for Improving Coherence Among Reactor Arena Risk-Informed Activities

Although a great deal of progress has been made towards risk-informing regulatory activities, the staff is aware that many existing regulations remain inconsistent (or incoherent) with risk-informed practices. Many NRC regulations and processes have evolved in a less-than-integrated manner over the years. For example, the risk-informed significance determination processes used to evaluate performance deficiencies under the current reactor oversight program (ROP) have identified numerous regulations for which non-compliance is not risk-significant. In addition, since risk was not assessed when most reactor design basis regulations were promulgated, use of the risk-informed ROP emphasizes safety issues not directly addressed in licensee Final Safety Analysis Reports or other docketed material. Furthermore, research and analysis over the years has revealed that some NRC regulations are overly conservative or unnecessarily burdensome without commensurate benefits to public safety. These regulations divert licensee and NRC resources away from more safety significant issues. There may also be inconsistencies between the approaches and the objectives that the staff has used to risk-inform different activities.

Consequently, the staff has been developing a program to address the coherence of regulatory activities. This program would provide an approach in which the reactor regulations, staff programs, and processes are built on a unified safety concept and are properly integrated so that they complement one another. An inter-office working group has been formed and is developing a detailed action plan for the program to improve coherence among risk-informed activities. The staff intends to engage stakeholders throughout the process.

Responding to a briefing by the staff on significant issues in the reactor safety arena, the Commission stated in a February 8, 2002, SRM that, in parallel to these staff activities, "in the next version of the RIRIP, the staff should provide its plan for moving forward with risk-informed regulation to address regulatory structure convergence with our risk-informed processes."

To complete this initiative, the staff will continue to investigate why there is not a common understanding of risk-informed regulatory objectives. Next, the staff will develop an overarching approach to provide a common structure for risk-informing activities. This approach will be based on the framework previously developed for risk-informing Part 50 that was presented in SECY-00-0198 ("Status Report on Study of Risk-Informed Changes to the Technical Requirements of 10 CFR Part 50 (Option 3) and Recommendations on Risk-Informed Changes to 10 CFR 50.44 (Combustible Gas Control)," dated September 14, 2000). The overarching approach will also utilize and expand the cornerstones developed by the reactor oversight program. The staff will use stakeholder input (such as NEI-02-02, "A Risk-Informed, Performance-Based Regulatory

Framework for Power Reactors,” dated May 2002, and related work now being funded by the Department of Energy) and will also solicit additional input.

Next, the staff will determine the desired characteristics of an integrated, risk-informed regulatory structure. These characteristics will be derived from the characteristics defined in SECY-98-300, “Options for Risk-Informed Revisions to 10 CFR Part 50 – ‘Domestic Licensing of Production and Utilization Facilities’,” dated December 23, 1998, and will be consistent with the philosophy outlined in the Commission White Paper on Risk-Informed, Performance-Based Regulation, dated March 11, 1999.

The staff then will evaluate risk-informed activities to identify inconsistencies and commonalities among activities and their desired characteristics, as noted above. We will look for safety concerns, inefficiencies, and unnecessary regulatory burden. Based on the results of the evaluation, we will set priorities and modify activities, as appropriate, so that they meet the desired characteristics. It should be noted that legitimate differences may exist among activities due to their particular purpose but that the activities should each contribute to the overarching goal of risk-informed regulation.

As noted above, the staff intends to engage stakeholders throughout the process. The detailed plan includes numerous public meetings and workshops. We will provide more details on the program to the Commission in a separate paper this fall. The staff anticipates that this paper will include a summary of its initial meetings with stakeholders and its thoughts on standardizing the terminology used in risk-informed applications and a common objective for the program.

In parallel with work to risk-inform operating reactor regulatory processes, the staff has been investigating approaches for making advanced reactor licensing more risk-informed. One part of the staff’s program to improve coherence will be an assessment of whether merging this advanced reactor framework development with operating reactor process improvements will result in a more efficient and effective outcome. While the staff previously planned to develop a paper to discuss an alternative regulatory framework for advanced reactor designs [SECY-01-088/WITS 200100109], the staff believes that it should be discussed in a future SECY, following the assessment. It is not yet clear that this will be the case because of a number of policy and technical issues unique to some advanced reactor design reviews. However, the staff is starting with the idea that a single, top-down approach is best, where differences between advanced reactors and operating reactors are addressed at a lower level in the framework. Some of these policy issues (e. g., whether current risk metrics are sufficient for all advanced reactor designs) are the subject of a future Commission paper.

PRA Steering Committee: Summary of Public Meetings

Since December 2001, the PRA Steering Committee (PRA SC) has held two public meetings to discuss ongoing efforts to risk-inform NRC regulatory activities. The NRC and the Nuclear Energy Institute (NEI) were the main participants in discussions at the meetings. Key topics of discussion are listed below.

PRA SC public meeting, December 4, 2001: Key items discussed included the PRA SC charter, status of Option 3 issues (50.44 rule language, decay heat petition status, LOOP/LOCA, and 50.46 progress), status of RISC 3 treatment under Option 2, PRA standards development (ASME

standard, RG 1.174), and progress on risk-informing technical specifications. The charter was discussed as a means of clarifying the PRA SC's mission to NEI.

PRA SC public meeting, April 24, 2002: Key items included Option 3 issues (general status, LOOP/LOCA redefinition, ECCS) and general direction or focus for Option 3. With regard to the latter, NEI indicated that existing projects should be completed before new research activities are begun. Other items discussed included RISC-3 SSCs rule language, risk-management technical specifications (formerly "risk-informed" technical specifications), and PRA standards development.

RIRIP Content and Organization

Part 1 of the RIRIP (Attachment 2) describes the plan's relationship to the PRA Policy Statement and its relevance to the NRC's Strategic Plan. Part 1 also discusses certain key features of the traditional deterministic approach that should be preserved in establishing risk-informed regulatory programs, since risk information will be used to complement the traditional approach. In addition, Part 1 provides draft guidance that the staff has used for selecting candidate requirements, practices, and processes to risk inform.

To complete the plan, Part 2 of the RIRIP describes the staff's risk-informed regulation activities, with chapters addressing the nuclear reactor safety arena and the nuclear materials and waste safety arenas. Each chapter is organized around the Strategic Plan strategies that are relevant to risk-informed regulation in the given arena(s). In addition, each chapter describes the implementation activities for each strategy and identifies significant milestones and training and communications considerations for each activity. Budgetary resources for each implementation activity are shown for Fiscal Year 2002 (as well as FY 2001 for some reactor activities). Relationships among implementation activities are described and critical path items are identified. Gantt charts for each implementation activity are also provided to illustrate the relationships among tasks within activities.

RESOURCES

In response to the Commission's direction regarding the October 2000 version of the RIRIP, the plan lists the priority rating of each risk-informed regulation implementation activity. These priorities were determined through the PBPM process and the FY 2002 resources listed in the plan have been budgeted by NRR, NMSS, and RES, consistent with their respective operating plans. The offices have different prioritization processes; however, each office uses the performance goals defined in the Agency's Strategic Plan to prioritize office activities as part of the budget process. As with other staff activities, changes to the resources allocated to implementation activities for risk-informed regulation will continue to be made consistent with the PBPM process to reflect changes to the Agency's budget and priorities.

COORDINATION

The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objections. The Office of the General Counsel has also reviewed this paper and has no legal objections.

/RA/

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- Attachments:
1. Table of Accomplishments
 2. Risk-Informed Regulation Implementation Plan

Table of Accomplishments	
Activity	Accomplishment
Reactor Oversight Process (ROP)	Based on its assessment of stakeholder feedback and the results and lessons learned from annual self-assessments, the staff has developed a much greater level of confidence that the ROP has met the Commission's direction to develop an oversight process that is more objective, risk-informed, understandable, and predictable. The most recent self assessment concluded that the risk-informed ROP helps the industry and the NRC to focus resources on areas of the most safety significance. The staff has identified areas for improvement of performance indicators and of the significance determination process and has developed plans to accomplish those improvements.
Guidance for risk-informed licensing basis changes	The staff issued a Regulatory Issue Summary that advised the industry of staff guidance for applying risk-informed decision making in the review of non-risk-informed license amendment requests. The staff has also prepared and is using guidance for the review of risk-informed licensing basis changes in the areas of graded quality assurance, inservice inspection, and inservice testing. Final update of this guidance is ongoing, but is dependent on progress in other areas, particularly special treatment requirements as discussed below.
Special Treatment Requirements	The staff developed draft rule language, obtained stakeholder feedback (from public meetings and by written comments), and is continuing to prepare the proposed rule package. In February, the staff provided comments to NEI on the proposed implementation guidance on categorization. In March 2002 the staff completed its interactions on pilot plant conduct of integrated decision making panel reviews of candidate systems. In April, the staff prepared draft staff review guidance for review of a PRA to be used in this application which was peer-reviewed using NEI 00-02.
10 CFR Part 50.44	The staff completed a detailed technical review that provided the basis for proposed risk-informed changes to the rule. The improved realism supports the agency's decision to eliminate requirements for equipment that is not important to safety. The Commission approved the staff's planned approach. The staff completed the proposed rulemaking package in May and provided it to the Commission for approval.
PRA Quality	The staff has been working closely with ASME, ANS, NFPA, and NEI to develop standards for PRA quality and PRA review. Since the December 2001 version of the RIRIP, ASME has issued its final standard for Level 1 and limited Level 2 PRA; ANS has continued to develop standards to address external hazards, low power/shutdown, and internal fire events; and NEI has issued its guidance on Level 1 and simplified Level 2 PRA peer review. The staff has begun writing a new regulatory guide and SRP chapter to endorse the ASME standard and related guidance.
10 CFR Part 50.46	The staff has nearly completed the technical studies for each of the proposed changes to 50.46 and its associated rules. The technical reports related to ECCS evaluation criteria (Appendix K), ECCS acceptance criteria, and ECCS functional reliability (GDC 35) are expected to be completed by July 2002. A report on one aspect of the ECCS reliability study, a plant-specific approach to assessing ECCS functional reliability, was delivered in May 2002 and is currently being reviewed by a working group dedicated to drafting the alternative rule to GDC 35. The long-term study related to estimating break frequency according to pipe size is still ongoing.
Risk-Informed Technical Specifications	The staff completed reviews of industry proposals to modify requirements related to surveillance requirements and preferred end states. Seven other industry initiatives have been proposed to the staff. Safety evaluations of two initiatives are in progress. Reviews of two other initiatives are ongoing.
Individual Plant Examination - External Events (IPEEE)	The staff completed its review of the industry's IPEEE submittals and an insights report was prepared. The IPEEE program was a success that resulted in the nuclear power industry identifying safety improvements that substantially reduced the risk of accidents. The generic insights from this effort will be used to support development of PRA guidance and standards, while plant-specific risk information will support the risk-informed reactor oversight program.

Table of Accomplishments	
Activity	Accomplishment
Reg. Guide 1.174/SRP Chapter 19	The staff completed its first revision of these documents since their initial publication in July 1998, with the following changes: <ol style="list-style-type: none"> 1. Risk related information may now be requested if new, unforeseen hazards emerge or prospects increase substantially for known hazards. 2. Indication was provided of on-going staff discussions on the effect of increases to fuel burn-up and changes to mixed-oxide fuel on risk metrics, such as large early release frequency. 3. Inclusion of additional examples of risk insights in the decision-making process.
NMSS Risk Case Studies	The eight case studies were completed in December 2001. As part of this effort, NMSS held several stakeholder meetings, including a meeting with a diverse set of Stakeholders in October 2001. Also, to gain a broader perspective of risk in the materials and waste arenas, the eight case studies were integrated with other related risk assessments. Major outcomes of the case study effort were: (1) development of a formal set of Screening Considerations that could be used to determine whether an NMSS regulatory activity should be risk-informed, (2) development of a guide for using the Screening Considerations, and (3) and formation of a framework for developing materials and waste safety goals.
Identification of Regulatory Activities Amenable to Increased Use of Risk-Information	Between January and April 2002, the Risk Task Group, in consultation with the NMSS Divisions, used the NMSS Screening Considerations to systematically identify NMSS regulatory activities that are amenable to being risk-informed. This identification of activities will serve as the NMSS road map towards comprehensively risk-informing its regulatory activities. Actual implementation of the activities will be planned, prioritized and budgeted through the PBPM process.
Development of Materials and Waste Safety Goals	As part of the case study effort, NMSS established the feasibility and usefulness of safety goals in the materials and waste arenas and developed a first draft of safety goals. NMSS and RES have initiated a joint effort to continue developing materials and waste safety goals and risk metrics, and to develop other tools, methods, data, guidance and standards necessary for implementing risk-informed approaches in NMSS.
NMSS Risk Training Program	NMSS has instituted training courses to advance the use of risk assessment and risk management into its day-to-day operations. Tier I and II training courses on risk assessment in NMSS and a Tier III course on quantitative frequency analyses are offered regularly. A Tier III course on byproduct materials system of risk analysis and evaluation has been developed and the pilot course will be offered in June 2002. Evaluation of Tier III training programs for risk specialists is ongoing.
NMSS Risk Communication plan	In April 2002, NMSS revised the "Communication Plan for Risk Informing Materials and Waste Regulations." The Communication Plan describes NMSS' plan for communicating risk information to internal and external stakeholders. The purpose of the plan is (1) to communicate, to external stakeholders, the major points of the program to risk inform materials regulations, in order to increase public confidence, and (2) to communicate, within the NRC, the NMSS Risk Task Group's activities, to increase understanding and acceptance of NMSS's risk-informing efforts and to assist NMSS staff in communicating risk-related information to external stakeholders.
Risk-informed, Performance-based Temporary Instruction for the Nuclear Medicine Program	The staff's medical pilot program (nuclear medicine program) to streamline inspection and enforcement of materials licensees was completed in January 2002 with the results of the pilot program reported to the commission. A risk-informed, performance-based Temporary Instruction (TI) for the medical pilot program used a focus element approach to assess a licensee's performance relative to desired safety-related outcomes. The approach is expected to reduce unnecessary regulatory burden through more efficient and effective inspections. The pilot was successful in reducing direct inspection hours and making the inspections more consistent. Because of the success, the temporary instruction was extended until the inspection procedures are changed to incorporate all of the Materials Phase II changes.

Table of Accomplishments	
Activity	Accomplishment
Part 70 Integrated Safety Analyses	In accordance with the revised 10 CFR Part 70, each licensee has submitted a plan for conducting its Integrated Safety Analysis (ISA) for NRC staff review. The NRC staff has reviewed and approved two of the six plans. The NRC staff anticipates approving the remaining four plans during the summer of 2002. With much stakeholder involvement, the 10 CFR Part 70 Standard Review Plan was finalized in December 2001 and published in March 2002.
Fuel Cycle Oversight Revision Project	In March 2002, the staff provided the Commission a status report on the fuel cycle oversight revision project. This project will be closed at the end of FY 2002, after the staff completes near-term revisions of the Licensee Performance Review process and the guidance for conducting the fuel cycle facility inspection program. Beginning in FY 2003, risk-informed revisions to the fuel cycle oversight program's inspection procedures will be made during normal updates of the inspection program, commensurate with the implementation of the Part 70 revisions. Under this approach, the fuel cycle facility oversight process will evolve in a more risk-informed direction over the next several years.
10 CFR Part 63	The staff published the final risk-informed, performance-based rule for disposal of high-level radioactive wastes in the proposed geologic repository at Yucca Mountain, Nevada.
10 CFR Part 63 Guidance	The staff published in March 2002 the NUREG-1804, Revision 2, "Yucca Mountain Review Plan (Draft Report for Comment)." The review plan provides guidance to staff on implementing the risk-informed, performance-based regulations of Part 63.
Decommissioning Guidance Consolidation	The Decommissioning Guidance Consolidation Project is reviewing and consolidating existing decommissioning guidance, updating and risk-informing the guidance, as appropriate, in the process. Staff held a public workshop in June 2001 to solicit feedback from the public and stakeholders on the project. Also, staff convened the Volume 1 writing team in June 2001. The staff published Volume 1 (Decommissioning Process) as NUREG-1757 for comment in January 2002. Volume 1 is expected to be issued in September 2002. The writing team for Volume 2 (Dose modeling) was convened in January 2002 and the draft will be issued for comment in September 2002.

Risk-Informed Regulation Implementation Plan

United States Nuclear Regulatory Commission
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PART 2. RISK-INFORMED REGULATION IMPLEMENTATION ACTIVITIES

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LIST OF ACRONYMS

ACNW	Advisory Committee on Nuclear Waste
ACRS	Advisory Committee for Reactor Safeguards
ALARA	as low as reasonably achievable
ANPR	advance notification of proposed rulemaking
ANS	American Nuclear Society
ASME	American Society of Mechanical Engineers
ASP	accident sequence precursor
BWR	boiling water reactor
BWROG	Boiling Water Reactor Owners Group
CCF	common-cause failure
CFR	<i>U.S. Code of Federal Regulations</i>
CRGR	Committee to Review Generic Requirements
CRMP	configuration risk management program
DOE	Department of Energy
DSI	direction-setting issue
EPA	Environmental Protection Agency
EPIX	equipment performance and information exchange
EPRI	Electric Power Research Institute
ET	executive team
FAVOR	probabilistic fracture mechanics code
FCSS	Fuel Cycle Safety and Safeguards
FSAR	final safety analysis report
FTE	full time employees
GL	generic letter
GQA	graded quality assurance
HRA	human reliability analysis
INPO	Institute of Nuclear Power Operations
IPEEE	individual plant examination - external events
IPE	individual plant examination
ISFSI	independent spent fuel storage installation
ISA	integrated safety analysis
ISI	inservice inspection
IST	inservice testing
LCO	limiting conditions for operation

LER	Licensee Event Report
LERF	large early release frequency
LOCA	loss of coolant accident
LPSD	low power/shut down
LRS	low-risk significant
LT	leadership team
MACCS	MELCOR accident consequence code system
MOR	Monthly Operating Report
NEI	Nuclear Energy Institute
NFPA	National Fire Protection Association
NMSS	NRC Office of Nuclear Material Safety and Safeguards
NRC	Nuclear Regulatory Commission
NRS	non-risk significant
NRR	NRC Office of Nuclear Reactor Regulation
OM	operation and maintenance
PA	performance assessment
PBPM	planning, budgeting, and performance management
PRA	probabilistic risk assessment
PRASC	PRA steering committee
PRM	petition for rulemaking
PTS	pressurized thermal shock
PER	pressurized-water reactor
QA	quality assurance
RADS	reliability and availability data system
RBI	risk-based performance indicators
RES	NRC Office of Research
RG	regulatory guide
RI	risk-informed
RILP	risk-informed licensing panel
RIPB	risk-informed performance-based
RIRIP	risk-informed regulation implementation plan
RIS	regulatory issue summary
ROP	reactor oversight process
RPV	reactor pressure vessel
RTG	Risk Task Group (NMSS)
SAPHIRE	Systems Analysis Program for Hands-on Integrated Reliability Evaluation
SCSS	sequence coding and search system
SDP	significance determination process
SFPO	Spent Fuel Project Office (NMSS)
SNM	special nuclear material

SPAR	standardized plant analysis risk
SRA	senior resident analyst
SRM	staff requirements memorandum
SRP	standard review plan
STP	South Texas Project
STS	standard technical specifications
SSC	structures, systems and components
TBD	to be determined
TI	temporary instruction
TMI	Three Mile Island
TTC	NRC Technical Training Center
WOG	Westinghouse Owners Group

FOREWORD

The Nuclear Regulatory Commission's (NRC's) policy for implementing risk-informed regulation was expressed in the 1995 policy statement on the use of probabilistic risk assessment (PRA) methods in nuclear regulatory activities. The policy statement says:

The use of PRA technology should be increased in all regulatory matters to the extent supported by the state-of-the-art in PRA methods and data and in a manner that complements the NRC's deterministic approach and supports the NRC's traditional defense-in-depth philosophy.

PRA and associated analyses (e.g., sensitivity studies, uncertainty analyses, and importance measures) should be used in regulatory matters, where practical within the bounds of the state-of-the-art, to reduce unnecessary conservatism associated with current regulatory requirements, regulatory guides, license commitments, and staff practices. Where appropriate, PRA should be used to support the proposal of additional regulatory requirements in accordance with 10 CFR 50.109 (Backfit Rule). Appropriate procedures for including PRA in the process for changing regulatory requirements should be developed and followed. It is, of course, understood that the intent of this policy is that existing rules and regulations shall be complied with unless these rules and regulations are revised.

PRA evaluations in support of regulatory decisions should be as realistic as practicable and appropriate supporting data should be publicly available for review.

The Commission's safety goals for nuclear power plants and subsidiary numerical objectives are to be used with appropriate consideration of uncertainties in making regulatory judgements on the need for proposing and backfitting new generic requirements on nuclear power plants licensees.

The Commission also said -

Given the dissimilarities in the nature and consequences of the use of nuclear materials in reactors, industrial situations, waste disposal facilities, and medical applications, the Commission recognizes that a single approach for incorporating risk analyses into the regulatory process is not appropriate. However, PRA methods and insights will be broadly applied to ensure that the best use is made of available techniques to foster consistency in NRC risk-based decision-making.

In issuing the policy statement, the Commission said it expected that implementation of the policy statement would improve the regulatory process in three ways: by incorporating PRA insights in regulatory decisions, by conserving agency resources, and by reducing unnecessary burden on licensees.

In the March 1999 report "Nuclear Regulation-Strategy Needed to Regulate Safety Using Information on Risk" (GAO/RCED-99-95), the General Accounting Office made the following recommendation:

To help ensure the safe operation of plants and the continued protection of public health and safety in a competitive environment, we recommend that the Commissioners of NRC direct the staff to develop a comprehensive strategy that includes but is not limited to objectives, goals, activities, and time frames for risk-informed regulation; specifies how the Commission expects to define the scope and implementation of risk-informed regulation; and identifies the manner in which it expects to continue the free exchange of operational information necessary to improve the quality and reliability of risk assessments.

In a January 2000 memorandum to the Commission, the staff outlined a strategy for risk-informed regulation. In March 2000, the staff gave the Commission an initial version of the Risk-Informed Regulation Implementation Plan (RIRIP). The Commission reviewed the plan and, after a March briefing by the staff, directed the staff in April 2000 to include in the next update of the implementation plan, an internal communications plan, training requirements for the staff, and a discussion of internal and external factors that may impede risk-informed regulation. The October 2000 version of the implementation plan was the first complete version, the purpose of which was to integrate the Commission's risk-informing activities and include the supplementary material the Commission asked for in April 2000.

The Commission was briefed by the NRC staff on the RIRIP on November 17, 2000. Subsequently, on January 4, 2001, the Commission requested that the staff more clearly indicate the priorities of the activities; provide a more detailed communication plan; identify resources and tools needed; address how performance-based regulatory approaches will be integrated into the process of risk-informing regulations; and identify the items that are critical path and have cross-cutting dimensions.

Organization of the RIRIP

The RIRIP consists of two parts. Part 1 provides a general discussion of risk-informed regulation applicable to three of the primary strategic arenas. Part 1 first discusses the relevance of the RIRIP to the Agency's Strategic Plan, and provides general guidelines for identifying "candidate" requirements, practices, and process that may be amenable to, and benefit from, an increased use of risk insights. Part 1 then provides a discussion of factors to consider in risk-informing the Agency's activities, including defense-in-depth, safety margins, the ALARA principle, and safety goals. Finally, Part 1 provides a general discussion of communications plans and training programs.

Part 2 of the plan describes the staff's activities for risk-informed regulation that are specific to the strategic arenas and is based on the Commission's strategic plan, with chapters on the Nuclear Reactor Safety arena, Nuclear Materials Safety arena, and Nuclear Waste Safety arena. Each chapter is organized around the strategic plan strategies relevant to risk-informed regulation in that arena. The implementation activities for each strategy are described, significant milestones are listed, and milestones schedules are noted. Progress in completing established milestones is also discussed.

Certain implementation activities in the reactor safety, materials safety, and waste safety arenas may substantially differ in scope, form, and content. This is because the nature of the activities being regulated varies greatly, as does the availability of risk assessment methods. It should also

be noted that this plan condenses the more detailed descriptions of staff activities in various Commission papers, program plans, and office operating plans.

Part I. Risk-Informed Regulation

The NRC has for many years developed and adapted methods for doing probabilistic risk assessments (PRAs) and performance assessments (PAs) to better understand risks from licensed activities. The NRC has supported development of the science, the calculation tools, the experimental results, and the guidance necessary and sufficient to provide a basis for risk-informed regulation. By the mid-1990s, the NRC had a sufficient basis to support a broad range of regulatory activities. The Commission's 1995 PRA policy statement provides guidance on risk-informing regulatory activities. In this policy statement, the Commission said that "the use of PRA technology should be increased in all regulatory matters to the extent supported by the state-of-the-art in PRA methods and data and in a manner that complements the NRC's deterministic approach and supports the NRC's traditional defense-in-depth philosophy." This plan implements that policy.

In the policy statement, the Commission said it expected implementation of the policy statement would improve the regulatory process in three ways: by incorporating PRA insights in regulatory decisions, by conserving agency resources, and by reducing unnecessary burden on licensees. The movement toward risk-informed regulation has indeed sharpened the agency's (and, therefore, the licensees') focus on safety, reduced unnecessary regulatory burden, and an effective, efficient regulatory process. A collateral benefit is the opportunity to update the technical bases of the regulations to reflect advances in knowledge and methods and decades of operating experience. In line with the NRC's goal of increasing public confidence, the agency is considering risk-informed regulation openly, giving the public and the nuclear industry clear and accurate information and a meaningful role in the process.

In 1998 the agency formally defined risk-informed regulation as an approach to regulatory decision-making that uses risk insights as well as traditional considerations to focus regulatory and licensee attention on design and operational issues commensurate with their importance to health and safety. A risk-informed approach enhances the traditional approach by: (a) explicitly considering a broader range of safety challenges; (b) prioritizing these challenges on the basis of risk significance, operating experience, and/or engineering judgment; (c) considering a broader range of counter measures against these challenges; (d) explicitly identifying and quantifying uncertainties in analyses; and (e) testing the sensitivity of the results to key assumptions. A risk-informed regulatory approach can also be used to identify insufficient conservatism and provide a basis for additional requirements or regulatory actions.

1. Relevance to the Strategic Plan

While the PRA policy statement and other risk-informed regulatory initiatives were being developed, the NRC also developed a strategic plan for accomplishing its mission. The strategic plan sets strategic and performance goals and strategies for four strategic arenas: Nuclear Reactor Safety, Nuclear Materials Safety, Nuclear Waste Safety, and International Nuclear Safety Support. The agency has established four performance goals for the Nuclear Reactor Safety, Nuclear Materials Safety, and Nuclear Waste Safety arenas: (1) to maintain safety and protect the environment and the common defense and security, (2) to increase public confidence, (3) to make

NRC activities and decisions more effective, efficient, and realistic, and (4) to reduce unnecessary regulatory burden. The strategic plan guides the agency's initiatives to support risk-informed regulation by defining strategic goals, performance goals and measures, and "strategies." The RIRIP specifies ongoing or planned activities to implement strategic plan strategies for risk-informed regulation. It also specifies:

- draft criteria for risk-informing a program, practice, or requirement
- factors to consider in risk-informing a program, practice, or requirement
- relevance to performance-based regulation

The purpose of this plan is to integrate the Commission's risk-informing activities by identifying requirements and practices to be risk-informed and the necessary data, methods, guidance, and training. This plan is also intended to explain the agency's risk-informed regulatory policy to the public and the nuclear industry. The challenge in developing the RIRIP was to specify staff activities that are both necessary and sufficient to implement the strategic plan strategies. To show the relevance of the RIRIP to the strategic plan, the implementation activities and milestones in Part 2 of the RIRIP are described as implementing risk-informed regulatory strategies of the Strategic plan (see Figure 1).

2. Guidelines for Selecting "Candidate" Requirements, Practices, and Processes

As the Federal agency responsible for regulating the civilian applications of nuclear technology, the NRC licenses a wide range of activities, including nuclear power generation, nuclear materials disposal, transportation and storage, nuclear materials processing and fabrication, and industrial and medical applications. The staff has developed screening considerations for identifying regulatory activities that could benefit from risk information. Draft screening criteria were originally published in Federal Register Notices (65 FR 14323, 03/16/00, and 65 FR 54323, 09/07/00). The criteria were finalized as considerations after review of comments received at workshops and public meetings and of the staff's experience in their application. The final screening considerations are as follows:

- (1) Could a risk-informed regulatory approach help to resolve a question with respect to maintaining or improving the activity's safety?
- (2) Could a risk-informed regulatory approach improve the efficiency or the effectiveness of the NRC regulatory process?
- (3) Could a risk-informed regulatory approach reduce unnecessary regulatory burden for the applicant or licensee?
- (4) Would a risk-informed approach help to effectively communicate a regulatory decision?

If the answer to any of the above is yes, proceed to additional considerations; if not, the activity is considered to be screened out.

(5) Do information (data) and/or analytical models exist that are of sufficient quality or could they be reasonably developed to support risk-informing a regulatory activity?

If the answer to consideration 5 is yes, proceed to additional considerations; if not, the activity is considered to be screened out.

(6) Can startup and implementation of a risk-informed approach be realized at a reasonable cost to the NRC, applicant or licensee, and/or the public, and provide a net benefit?

If the answer to consideration 6 is yes, proceed to additional criteria; if not, the activity is considered to be screened out.

(7) Do other factors exist which would limit the utility of implementing a risk-informed approach?

If the answer to consideration 7 is no, a risk-informed approach may be implemented; if the answer is yes, the activity may be given additional consideration or be screened out.

These screening considerations were developed by NMSS for use in the materials and waste arenas. The Risk Management Operating Team will evaluate the proposed final criteria to determine their applicability to the reactor arena.

3. Factors to Consider in Risk-Informed Regulation

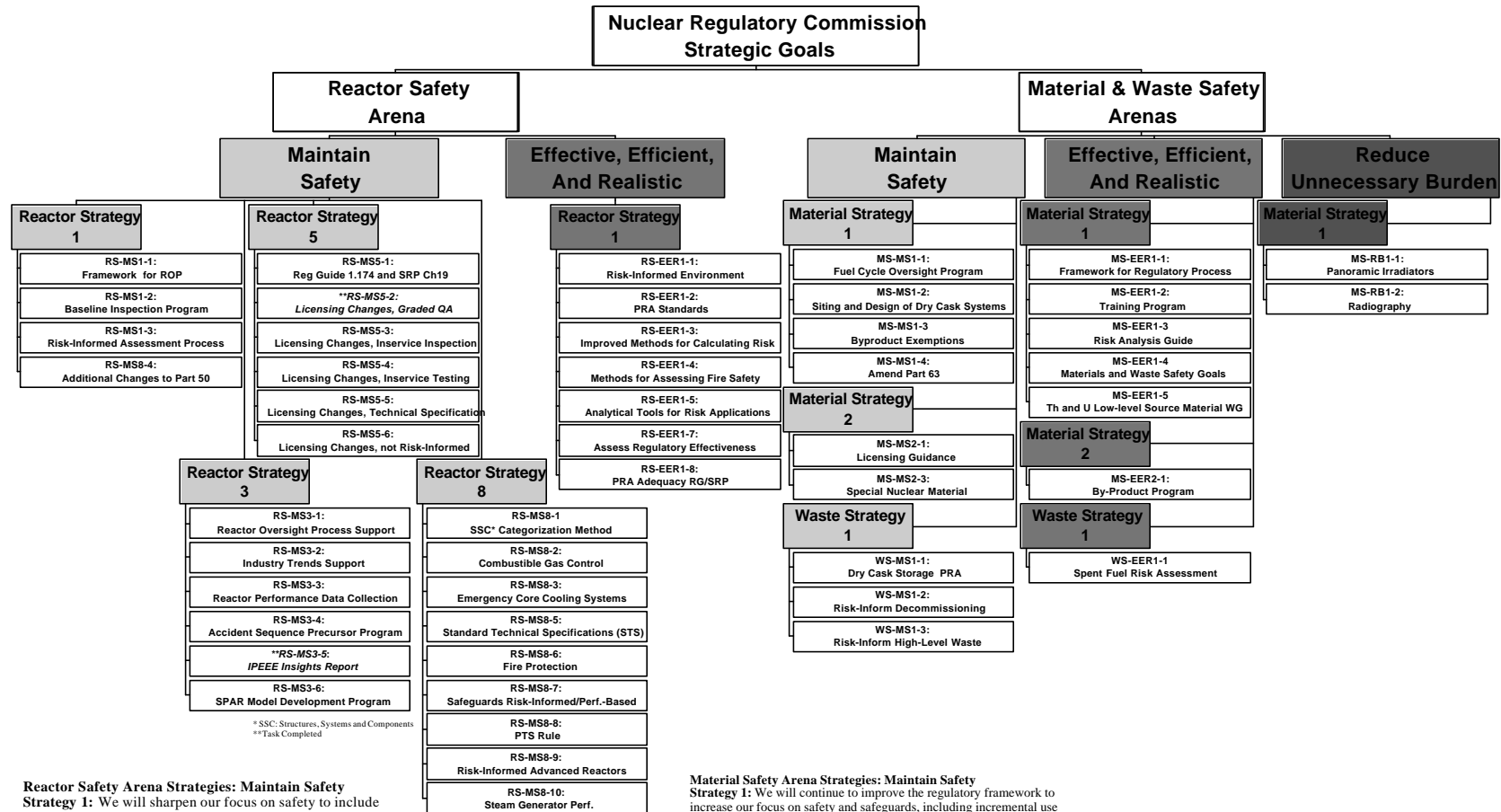
The NRC mission is to protect the public health and safety and protect the common defense and security in civilian applications of nuclear technology. Historically, the agency has used an effective, albeit often conservative, approach for regulatory decisions. To accomplish its mission, the agency has established a regulatory system which presumes that the public health and safety are adequately protected when licensees comply with regulations and license requirements. Regulations justified on the basis of adequate protection do not consider cost because they are required for safety, regardless of cost.

Since adequate protection is presumptively provided by existing regulations, the Commission has determined that, for nuclear power plants and fuel cycle facilities, proposed safety improvements beyond adequate protection should be adopted only if they provide “substantial” additional protection and the direct and indirect costs are justified. In the Nuclear Reactor Safety Arena, regulatory analysis guidelines and backfit analysis guidelines have been developed for assessing a “substantial” improvement and calculating cost-benefit. In the Nuclear Materials Safety Arena, the Commission has directed the staff to develop similar guidelines for fuel cycle facilities.

Risk-informed requirements must maintain reasonable assurance of adequate protection. A challenge in risk-informed regulation will be to maintain an acceptable level of safety while (1) improving effectiveness, efficiency, and realism in agency decisions, practices, and processes, (2) increasing public confidence in the agency, and (3) reducing unnecessary regulatory burden on licensees.

Figure 1

Risk-Informed Regulation Implementation Plan



* SSC: Structures, Systems and Components
**Task Completed

Reactor Safety Arena Strategies: Maintain Safety

Strategy 1: We will sharpen our focus on safety to include a transition to a revised NRC reactor oversight program for our inspection, assessment, and enforcement activities.

Strategy 3: We will evaluate operating experience and the results of risk assessments for safety implications.

Strategy 5: We will ensure that changes to operating licenses and exemptions to regulations maintain safety and meet regulatory requirements.

Strategy 8: We will continue to develop and incrementally use risk-informed and, where appropriate, less-prescriptive regulatory approaches to maintain safety.

Reactor Safety Arena Strategies: Effective, Efficient, and Realistic

Strategy 1: We will use risk information to improve the effectiveness and efficiency of our activities and decisions.

Material Safety Arena Strategies: Maintain Safety

Strategy 1: We will continue to improve the regulatory framework to increase our focus on safety and safeguards, including incremental use of risk-informed and, where appropriate, less prescriptive performance-based regulatory approaches to maintain safety.

Strategy 2: We will continue authorizing licensee activities only after determining that these proposed activities will be conducted consistent with the regulatory framework.

Material Safety Arena Strategies: Effective, Efficient, and Realistic

Strategy 1: We will continue to improve the regulatory framework to increase our effectiveness, efficiency, and realism.

Strategy 2: We will identify, prioritize, and modify processes based on effectiveness reviews to maximize opportunities to improve those processes.

Material Safety Arena Strategies: Reduce Unnecessary Burden

Strategy 1: We will continue to improve our regulatory framework in order to reduce unnecessary regulatory burden.

Waste Safety Arena Strategies: Maintain Safety

Strategy 1: We will continue developing a regulatory framework to increase our focus on safety, including the incremental use of risk-informed and, where appropriate, less prescriptive performance-based regulatory approaches to maintain safety.

Waste Safety Arena Strategies: Reduce Unnecessary Burden

Strategy 1: We will continue to improve our regulatory framework in order to reduce unnecessary regulatory burden.

To establish a consistent approach, the following factors (discussed in the paragraphs below) should be considered in risk-informing an agency requirement or practice:

- Defense-in-Depth
- Safety Margins
- ALARA Principle
- Safety Goals
- Performance-Based Implementation
- Voluntary Alternatives versus Mandatory Requirements
- Selective Implementation
- Regulatory Oversight Activities
- Regulatory Analysis

Since risk information is to be used to complement the traditional deterministic approach, risk-informed activities must preserve certain key factors of the deterministic approach. Among these factors are the fundamental safety principles of defense-in-depth, safety margins, the principle of “as low as reasonably achievable” (ALARA), radiation protection, and the agency’s safety goals. The NRC has used these principles in its regulatory programs to maintain acceptable risk levels. They ensure that the nuclear industry is safe. In risk-informing its requirements and practices, the NRC must use these principles to complement risk information in ensuring that regulations focus on the issues important to safety and account for uncertainties affecting regulatory decisions.

Defense-in-Depth

Defense-in-depth is an element of the NRC's safety philosophy that employs successive measures to prevent accidents or mitigate damage if a malfunction, accident, or naturally caused event occurs at a nuclear facility. Defense-in-depth is a philosophy used by the NRC to provide redundancy for facilities with "active" safety systems, as well as the philosophy of a multiple-barrier approach against fission product releases. The defense-in-depth philosophy ensures that safety will not be wholly dependent on any single element of the design, construction, maintenance, or operation of a nuclear facility. The net effect of incorporating defense-in-depth into design, construction, maintenance, and operation is that the facility or system in question tends to be more tolerant of failures and external challenges.

The concept of defense-in-depth has always been and will continue to be a fundamental tenet of regulatory practice in the nuclear field. It is expected that defense-in-depth for reactors and nuclear materials (which includes activities involving disposal, transportation and storage, processing and fabrication, and industrial and medical applications) may need to be considered differently due to the greater diversity in materials licensed activities and to the differences in safety issues.

In its May 25, 2000 letter to Chairman Meserve, the Advisory Committee on Reactor Safeguards (ACRS) and the Advisory Committee on Nuclear Waste (ACNW) provided a perspective on the role of defense-in-depth in risk-informed regulation.

“The primary need for improving the implementation of defense-in-depth in a risk-informed regulatory system is guidance to determine how many compensatory measures are

appropriate and how good these should be. To address this need, we believe that the following guiding principles are important:

- Defense-in-depth is invoked primarily as a strategy to ensure public safety given the unquantified uncertainty in risk assessments. The nature and extent of compensatory measures should be related, in part, to the degree of uncertainty
- The nature and extent of compensatory measures should depend on the degree of risk posed by the licensed activity
- How good each compensatory measure should be is, to a large extent, a value judgement and, thus, a matter of policy."

The ACRS/ACNW letter further stated that in the reactor arena, defense-in-depth entailed "placing compensatory measures on important safety cornerstones to satisfy acceptance criteria for defined design-basis accidents that represent the range of important accident sequences." For the reactor arena, Regulatory Guide 1.174 states that consistency with the defense-in-depth philosophy will be preserved by ensuring that:

- a reasonable balance is preserved among prevention of accidents, prevention of barrier failure, and consequence mitigation,
- an over-reliance on programmatic activities to compensate for weaknesses in equipment or device design is avoided,
- system redundancy, independence, diversity are preserved commensurate with the expected frequency, consequences of challenges to the system, and uncertainties (e.g., no risk outliers),
- the independence of barriers is not degraded such that defenses against potential common cause failures of multiple barriers are preserved, and the potential for the introduction of new common cause failure mechanisms is assessed,
- defenses against human errors are preserved, and
- the intent of the fundamental design features is maintained.

The Advisory Committee on Reactor Safeguards (ACRS) has expressed concerns about the role that defense in-depth should have in a risk-informed regulatory scheme. The Committee cites instances in which "seemingly arbitrary appeals to defense-in-depth have been used to avoid making changes in regulations or regulatory practices that seemed appropriate in the light of results of quantitative risk analyses." The letter's attachment describes two models on the scope and nature of defense-in-depth. "In the structuralist model, defense-in-depth is primary, with PRA available to measure how well it has been achieved." (This is the model implicit in the agency's PRA Policy Statement and in Regulatory Guide 1.174 concerning risk-informed changes to reactor licensing bases.) In the rationalist model, "the purpose of defense-in-depth is to increase the degree of confidence in the results of the PRA or other analyses supporting the conclusion that adequate safety has been achieved. ...What distinguishes the rationalist model from the structural model is the degree to which it depends on establishing quantitative acceptance criteria, and then carrying formal analyses, including analysis of uncertainties, as far as the analytical methodology permits."

To define the role of defense-in-depth in risk-informed regulation and to establish a consistent and reasoned approach, the following considerations should be addressed:

- What elements of defense-in-depth should be independent of risk information; e.g.,
 - provide prevention and mitigation protection?
 - use of good engineering practices (e.g., codes and standards)?
 - number and nature of barriers to radiation release?
 - emergency plans and procedures?
- What elements of defense-in-depth should be dependent upon risk information; e.g.,
 - the balance between prevention and mitigation?
 - the number of barriers?
 - the need for redundancy, diversity, independence of systems?
 - the events that need to be considered in the design?
- Do the defense-in-depth considerations expressed in Regulatory Guide 1.174 apply?

Risk insights can make the elements of defense-in-depth clearer by quantifying them to the extent practicable. Although the uncertainties associated with the importance of some elements of defense may be substantial, the fact that these elements and uncertainties have been quantified can aid in determining how much defense makes regulatory sense. Decisions on the adequacy of or the necessity for elements of defense should reflect risk insights gained through identification of the individual performance of each defense system in relation to overall performance.

In implementing risk-informed changes to requirements or practices, the staff should ask:

- Is defense-in-depth commensurate with the risk and uncertainty associated with the estimate of risk?
- Is a reasonable balance preserved among accident prevention, radiation exposure prevention, and consequence mitigation?
- Is there over-reliance on programmatic activities to compensate for design weaknesses?
- Are redundancy, independence, and diversity of the system commensurate with the expected frequency and consequences of challenges to the system and with the uncertainties?
- Are defenses against potential common-cause failures preserved and have potential new common-cause failure mechanisms been assessed?
- Is the independence of barriers preserved?
- Are defenses against human errors preserved?

Safety Margins

Existing regulations were developed to ensure adequate safety margins to account for uncertainties in analyses and data and to ensure that adequate time is available to prevent the consequences of events. Safety margins are part of defense-in-depth; they assure safety in spite of uncertainties.

In the reactor arena, Regulatory Guide 1.174 states that acceptable risk-informed changes to a nuclear power reactor's licensing basis will be consistent with the principle that sufficient safety margins are maintained. Improved information from data analysis, research experiments, and the like suggest that excessive safety margins exist given the current state of knowledge and current uncertainties. As regulations in the reactor, materials, and waste arenas are evaluated to improve the focus on safety, regulations that foster excessive safety margins will be candidates for change.

To define the role that safety margins play in risk-informed regulation and to establish a consistent and reasoned approach, the following considerations should be addressed:

- How should safety margins be employed to account for uncertainties in engineering analysis:
 - best estimate analysis with conservative acceptance criteria?
 - specified confidence level?
 - role of codes and standards (i.e., do they inherently address safety margin)?
- How should safety margins be employed to account for uncertainty in risk:
 - parameter uncertainty; defense-in-depth (i.e., redundancy, diversity, independence)?
 - incompleteness in risk analysis (e.g., engineering judgment)?
 - model uncertainty (e.g., conservative acceptance criteria)?

In making risk-informed changes to requirements or practices, the staff should ask:

- What safety margins are acceptable given the risk significance of the regulated activity and uncertainties?
- Is the proposed change consistent with the principle that sufficient, realistic safety margins be maintained?
- Is there a method for evaluating whether safety margins will be adequately maintained?

The ALARA Principle

Consistent with the linear hypothesis of radiation protection, licensees are expected to keep radiation releases as low as reasonably achievable (ALARA). Conservatism introduced by applying the ALARA principle compensates for uncertainties about the precise point at which no adverse health effects occur.

The 1972 report of the Advisory Committee on the Biological Effects of Ionizing Radiation (BEIR) contended that, in the absence of better data, there was no reasonable alternative to a linear hypothesis of radiation protection. The linear hypothesis assumes a straight-line correlation between dose and somatic damage and does not allow for a threshold below which no injury will occur. Indeed, the linear hypothesis might overestimate the risks by failing to account for the effects of dose rate and cell repair. The 1990 BEIR-V report reaffirmed that the linear, no-threshold model of cancer risk (other than leukemia) was most consistent with the data. Consequently, licensees are expected to keep radiation releases to a level as low as reasonably achievable. In keeping with this philosophy of "as low as reasonably achievable," the staff seeks to strike a balance that considers the capabilities of technology and the costs of equipment while providing ample protection to the public. That is, the staff takes into account "the state of technology, and the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to the utilization of atomic energy in the public interest."

In making risk-informed changes to requirements or practices, the staff should ask:

- Is the risk-informed change consistent with the ALARA principle?
- If the ALARA principle is not used, how are limits set?

Safety Goals

In general, a safety goal is useful to define the desired level of safety. In the reactor arena, safety goals were established to define "how safe is safe enough" or, in other words, when additional regulation is not warranted. The Agency uses these goals as benchmarks for calculated risk measures. The Commission has directed the staff to develop safety goals for the materials and waste safety arenas similar to the reactor safety goals, and it is expected they will be used in a similar capacity.

In risk-informing requirements or practices, the staff should ask:

- Does the practice provide a level of safety commensurate with applicable safety goals?

Performance-Based Implementation

The agency has defined a performance-based requirement as one that relies upon measurable (or calculable) outcomes (i.e., performance results) to be met, while providing flexibility to the licensee as to the means of meeting these outcomes. SECY-00-0191 (dated September 1, 2000) lists high-level guidelines that are intended to promote the use of a performance-based regulatory framework throughout the agency. In general, a performance-based regulatory approach focuses on results as the primary basis for regulatory decision-making and as such allows licensee flexibility in meeting a regulatory requirement. This in turn can result in a more efficient and effective regulatory process.

The staff plans to develop guidance to incorporate the high-level guidelines into internal NRC procedures and to apply the guidelines to future regulatory initiatives, including those that are identified through risk-informed activities.

To the extent appropriate, staff activities to risk-inform regulations should also incorporate the performance-based approach to regulation. The corollary is also true; performance-based regulations should be risk-informed when possible. Figure 2 illustrates that both risk-informed and performance-based approaches will be pursued as appropriate when modifying the regulatory framework.

In assessing performance-based implementation of risk-informed regulations, the staff should ask:

- Are there measurable or calculable parameters and criteria for judging the licensee's or the system's performance?
- Can the risk-informed change be made as a performance-based change?

Voluntary Alternatives versus Mandatory Requirements

The Commission has promulgated several regulations which permit reactor licensees to voluntarily implement risk-informed requirements or continue to operate under current requirements. The decision as to whether to provide licensees this choice is determined by the backfit rule and safety considerations. In risk-informing the agency's regulations, the staff may identify areas where

mandatory requirements are warranted. The staff will evaluate proposed new requirements in line with existing guidance.

In considering voluntary versus mandatory implementation of risk-informed regulation, the staff should ask:

- Should all applicable licensees be required to implement the revised, risk-informed regulation? (If so, have the criteria of 10 CFR Part 50.109, the Commission's backfit rule, been met?)
- Should the regulation offer licensees alternative requirements?
- If staff practices are risk informed, are they mandatory or voluntary?

Selective Implementation

The issue is whether licensees that wish to use risk-informed options may selectively implement risk-informed requirements or must implement them all. Currently, selective implementation is decided on a case-by-case basis.

In weighing selective implementation of risk-informed changes to requirements or practices, the staff should ask:

- Are there acceptable methods for assessing the effect of selective implementation on safety?
- Would selective implementation decrease the agency's efficiency and effectiveness?
- In general, what limits, if any, should be placed on selective implementation?

Regulatory Oversight Activities

The agency's regulatory oversight activities consist of inspection, assessment (e.g., through use of performance indicators), or enforcement. The staff should consider the implications of risk-informed regulatory changes on regulatory oversight activities and ask of every risk-informed regulation:

- Would licensee compliance with the risk-informed regulation be amenable to regulatory oversight?
- Would the risk-informed regulation increase the number or complexity of inspections needed to ensure compliance?
- Would the risk-informed regulation necessitate changes in the agency's oversight program?
- Would assessment or monitoring be required?

Regulatory Analysis

The NRC performs regulatory analyses to support numerous NRC actions affecting reactor and materials licensees. In general, each NRC office ensures that all mechanisms used by the staff to establish or communicate generic requirements, guidance, requests, or staff positions that would affect a change in the use of resources by its licensees, include an accompanying regulatory analysis. In regard to relaxation of requirements, NUREG/BR-0058 states that a regulatory analysis "should provide that level of assessment that will demonstrate with sufficient reasonableness that the two following conditions are satisfied:

- The public health and safety and the common defense and security would continue to be adequately protected if the proposed reduction in requirements or positions were implemented
- The cost savings attributed to the action would be substantial enough to justify taking the action”

As part of the staff's activities, the role of regulatory analysis in evaluation risk-informed regulatory changes will be established to ensure a consistent and predictable regulatory framework.

4. Communication Plans

The agency recognizes that it must keep its staff, the public, and the nuclear industry informed about its regulatory activities. The staff has recognized the need to provide communication plans that will increase public confidence by conveying information about the agency's programs and activities to the public. Specifically, integrated arena-specific communication plans that cut across organizational boundaries and address the broad spectrum of agency efforts to risk-inform regulatory activities are needed, as well as activity-specific plans.

In response to this, the staff of NMSS prepared and submitted to the OEDO in December 2000 a communication plan for risk-informing the regulatory activities in the materials and waste safety arenas. The stated purposes of the NMSS communication plan were (1) to communicate the major points of the program to risk-inform materials (and waste) regulations in order to increase public confidence in the NMSS efforts, and (2) to communicate NMSS activities, tasks, and methodology in a manner that increases understanding and acceptance of NMSS efforts within the NRC and assists colleagues in their task of presenting risk-related information. NMSS revised its communication plan in April 2002. NRR and RES intend to develop a similar plan for the reactor safety arena.

Over the past year, formal communication plans were also developed for several activity-specific programs, including the fuel cycle facility oversight process, high-level waste, the nuclear material inspection program, the reactor oversight process, reactor safeguards and security, and South Texas Project activities.

More information regarding the reactor oversight process plan and specific guidance for developing communications plans are provided in the following memoranda:

- Memorandum from William D. Travers, Executive Director for Operations, regarding Communication Activities, May 1, 2000.
- Memorandum from William D. Travers, Executive Director for Operations, regarding Next Steps Toward Completing Communication Plans, July 19, 2000.

The individual activity descriptions in Part 2 of the RIRIP indicate whether the staff has developed a communication plan specific to the activity or the general regulatory area.

5. Training Program

In the Nuclear Reactor Safety arena, the staff has already been given general training to increase its knowledge of and skills in probabilistic risk assessment. Training is available on a continual, as-needed basis. Additional training is being provided on certain risk-informed regulatory initiatives such as the revised reactor oversight process. In the Nuclear Materials Safety and Nuclear Waste Safety arenas, the NRC's Office of Human Resources is identifying, developing, and implementing staff training to ensure that the staff is fully prepared for risk-informed regulation. Training activities are described in further detail in Part 2.

Part 2. Risk-Informed Regulation Implementation Activities

Part 2 of the RIRIP presents current risk-informed initiatives and activities in the reactor safety, materials safety, and waste safety arenas. Part 2 of the RIRIP is presented in two chapters: Chapter 1 addresses the reactor safety arena, and Chapter 2 addresses the nuclear materials and waste safety arenas. (For clarity, the materials and waste arenas are presented together since NMSS has primary responsibility for both.) At the beginning of each chapter is a narrative describing the general plan for increasing the use of risk insights in regulatory activities.

Each chapter provides individual, detailed discussions of the implementation activities, including project management considerations and more detailed schedule and milestone information. Figure 1 shows the format of each activity discussion provided in Chapters 1 and 2.

To highlight activity interrelationships, a list is provided below of all of the RIRIP activities and any cross-cutting activities identified by RES, NRR, and NMSS. For example, the first activity listed is RS-MS1-1 for which nine activities were identified as related in some way (or cross-cutting). Within each activity are critical path milestones that must be accomplished for that activity to be completed. The activity milestones are shown on the schedules (Gantt charts) associated with each of the activity descriptions presented in Chapters 1 and 2 of this Part.

Reactor Arena

RS-MS1-1 Establish a framework for deciding on inspection, assessment, and enforcement action for nuclear power reactors that focuses on activities and systems that are risk-significant

- RS-MS1-2 Inspection Program
- RS-MS1-3 Assessment Process
- RS-MS3-1 ROP Support
- RS-MS3-2 Industry Trends Support
- RS-MS3-4 ASP
- RS-MS3-6 SPAR Models
- MS-MS1-1 Fuel Cycle Oversight
- MS-EER1-1 Risk-Informing NMSS Regulatory Process

RS-MS1-2 Risk-inform the baseline inspection program for all nuclear power plants with additional inspections that may be performed in response to a specific event or problem at a plant

- RS-MS1-1 Reactor Oversight Process
- RS-MS1-3 Assessment Process

RS-MS1-3 Maintain a risk-informed assessment process for determining NRC actions based upon performance indicator and inspection information

- RS-MS1-1 Reactor Oversight Process
- RS-MS1-2 Inspection Program
- RS-MS3-1 ROP Support
- RS-MS3-2 Industry Trends Support
- RS-MS3-3 Reactor Performance Data Collection
- RS-MS3-6 SPAR Models
- RS-EER1-7 Regulatory Effectiveness

RS-MS3-1 Reactor Oversight Process Support

- RS-MS1-1 Reactor Oversight Process
- RS-MS1-3 Assessment Process
- RS-MS3-3 Reactor Performance Data Collection

RS-MS3-2 Industry Trends Support

- RS-MS1-1 Reactor Oversight Process
- RS-MS1-3 Assessment Process
- RS-MS3-3 Reactor Performance Data Collection
- RS-MS3-4 ASP Analyses
- RS-EER1-5 Maintain Analytical Tools
- RS-MS3-6 SPAR Models
- RS-EER1-7 Regulatory Effectiveness

RS-MS3-3 Reactor Performance Data Collection Program

- RS-MS1-3 Assessment Process
- RS-MS3-1 ROP Support
- RS-MS3-2 Industry Trends Support
- RS-MS3-4 ASP Analyses
- RS-MS8-1 Special Treatment Requirements
- RS-MS8-8 PTS Rule
- RS-MS8-10 Steam Generators
- RS-EER1-3 Improved Methods of Calculating Risk
- RS-EER1-4 Fire Safety Methods
- RS-EER1-5 Maintain Analytical Tools
- RS-MS3-6 SPAR Models
- RS-EER1-7 Regulatory Effectiveness

RS-MS3-4 Accident Sequence Precursor Program

- RS-MS1-1 Reactor Oversight Process
- RS-MS3-2 Industry Trends Support
- RS-MS3-3 Reactor Performance Data Collection
- RS-MS3-6 SPAR Models
- RS-EER1-7 Regulatory Effectiveness

RS-MS3-5 Review IPEEE submittals and issue insights report

- RS-MS1-1 Reactor Oversight Process
- RS-MS1-3 Assessment Process
- RS-MS5-1 RG 1.174 and SRP 19
- RS-MS8-9 Advanced Reactors
- RS-EER1-2 PRA Standards Development
- WS-MS1-1 Dry Cask PRA
- WS-MS1-3 High-Level Waste Regulatory Framework

RS-MS3-6 SPAR Model Development Program

- RS-MS1-1 Reactor Oversight Process
- RS-MS1-3 Assessment Process
- RS-MS3-2 Industry Trends Support
- RS-MS3-3 Reactor Performance Data Collection
- RS-MS3-4 ASP Analyses
- RS-EER1-3 Improved Methods of Calculating Risk
- RS-EER1-5 Maintain Analytical Tools
- RS-EER1-8 PRA Adequacy Reg Guide

RS-MS5-1 Establish guidance for risk-informed licensing basis changes: Update Regulatory Guide 1.174 and SRP Chapter 19

- RS-MS5-3 Licensing Basis Changes: Inservice Inspection
- RS-MS5-4 Licensing Basis Changes: Inservice Testing
- RS-MS5-5 Licensing Basis Changes: Technical Specifications
- RS-MS5-6 Licensing Basis Changes: Non Risk-Informed Guidance
- RS-EER1-8 PRA Adequacy Reg Guide
- RS-EER1-2 PRA Standards Development
- RS-EER1-3 Improved Methods of Calculating Risk
- MS-EER1-1 Risk-Informing NMSS Regulatory Process
- WS-MS1-2 Decommissioning Regulatory Framework
- WS-MS1-3 High-Level Waste

RS-MS5-2 Establish application-specific guidance for risk-informed licensing basis changes: Updating the Graded QA RG

- RS-MS5-1 RG 1.174 and SRP 19
- RS-EER1-8 PRA Adequacy Reg Guide

RS-MS5-3 Establish application-specific guidance for risk-informed licensing basis changes: Risk-Informed Inservice Inspection

- RS-MS5-1 RG 1.174 and SRP 19
- RS-MS8-8 PTS Rule Revision
- RS-EER1-8 PRA Adequacy Reg Guide

RS-MS5-4 Establish application-specific guidance for risk-informed licensing basis changes: Inservice Testing

- RS-MS5-1 RG 1.174 and SRP 19
- RS-EER1-8 PRA Adequacy Reg Guide

RS-MS5-5 Establish application-specific guidance for risk-informed licensing basis changes:
Technical Specifications

- RS-MS5-1 RG 1.174 and SRP 19
- RS-EER1-8 PRA Adequacy Reg Guide

RS-MS5-6 Establish guidance for risk-informed licensing basis changes: guidance for use when reviewing non-risk-informed submittals

- RS-MS5-1 RG 1.174 and SRP 19
- RS-EER1-8 PRA Adequacy Reg Guide

RS-MS8-1 Develop an alternative risk-informed approach to special treatment requirements in Part 50 that would vary the treatment applied to structures, systems and components (SSC) on the basis of their safety significance using a risk-informed categorization method

- RS-MS3-3 Reactor Performance Data Collection
- RS-MS8-4 Additional Changes to Part 50
- RS-EER1-2 PRA Standards Development
- RS-EER1-8 PRA Adequacy Reg Guide

RS-MS8-2 Change technical requirements of 10 CFR 50.44 (“Standards for Combustible Gas Control in Light-Water-Cooled Power Reactors”)

- No cross-cutting activities identified.

RS-MS8-3 Change technical requirements of 10 CFR 50.46 (“Acceptance Criteria for Emergency Core Cooling Systems for Light-Water Nuclear Power Reactors”)

- RS-EER1-2 PRA Standards Development
- RS-MS8-5 Standard Technical Specifications

RS-MS8-4 Evaluate the feasibility of additional changes to the technical requirements of 10 CFR Part 50

- RS-MS8-1 Special Treatment Requirements
- RS-EER1-8 PRA Adequacy Reg Guide

RS-MS8-5 Plan and implement risk-informed standard technical specifications (STS)

- RS-MS8-3 Emergency Core Cooling Systems
- RS-EER1-2 PRA Standards Development

RS-MS8-6 Fire protection for nuclear power plants

- RS-EER1-2 PRA Standards Development
- RS-EER1-4 Fire Safety Methods

RS-MS8-7 Develop alternative requirements for safeguards that are risk-informed and/or performance-based

- WS-MS1-2 Decommissioning Regulatory Framework

RS-MS8-8 Develop the technical basis to revise the PTS rule

- RS-MS3-3 Reactor Performance Data Collection
- RS-MS5-3 Licensing Basis Changes: Inservice Inspection
- RS-EER1-3 Improved Methods of Calculating Risk
- RS-EER1-5 Maintain Analytical Tools

RS-MS8-9 PRA Review of advanced reactor applications

- RS-EER1-3 Improved Methods of Calculating Risk
- RS-EER1-5 Maintain Analytical Tools

RS-MS8-10 Develop methods for assessing steam generator performance during severe accidents

- RS-MS3-3 Reactor Performance Data Collection
- RS-EER1-2 PRA Standards Development
- RS-EER1-3 Improved Methods of Calculating Risk
- RS-EER1-5 Maintain Analytical Tools

RS-EER1-1 Creating a risk-informed environment

- Relates generally to all NRC efforts to risk-inform its regulatory activities.

RS-EER1-2 Develop standards for the application of risk-informed, performance-based regulation in conjunction with national standards committees

- RS-MS5-1 RG 1.174 and SRP 19
- RS-MS8-1 Special Treatment Requirements
- RS-MS8-3 Emergency Core Cooling Systems
- RS-MS8-4 Additional Changes to Part 50
- RS-MS8-5 Standard Technical Specifications
- RS-EER1-3 Improved Methods of Calculating Risk
- RS-EER1-4 Fire Safety Methods
- RS-EER1-5 Maintain Analytical Tools
- RS-EER1-8 PRA Adequacy Reg Guide
- MS-EER1-1 Risk-Informing NMSS Regulatory Process

RS-EER1-3 Develop improved methods for calculating risk in support of risk-informed regulatory decision making

- RS-MS5-1 RG 1.174 and SRP 19
- RS-MS8-8 PTS Rule Revision
- RS-MS8-10 Steam Generators
- RS-EER1-2 PRA Standards Development
- RS-EER1-4 Fire Safety Methods
- RS-EER1-5 Maintain Analytical Tools
- RS-MS3-6 SPAR Models
- RS-EER1-8 PRA Adequacy Reg Guide
- WS-MS1-1 Dry Cask PRA

RS-EER1-4 Develop and apply methods for assessing fire safety in nuclear facilities

- RS-MS3-3 Reactor Performance Data Collection
- RS-MS8-6 Fire Protection
- RS-EER1-2 PRA Standards Development
- RS-EER1-3 Improved Methods of Calculating Risk
- RS-EER1-5 Maintain Analytical Tools
- RS-EER1-8 PRA Adequacy Reg Guide
- WS-MS1-1 Dry Cask PRA

RS-EER1-5 Develop and maintain analytical tools for staff risk applications

- RS-MS3-2 System Reliability and Related Studies
- RS-MS3-3 Reactor Performance Data Collection
- RS-MS8-10 Steam Generators
- RS-EER1-3 Improved Methods of Calculating Risk
- RS-EER1-4 Fire Safety Methods
- RS-MS3-6 SPAR Models
- RS-EER1-8 PRA Adequacy Reg Guide
- WS-MS1-1 Dry Cask PRA

RS-EER1-7 Assess regulatory effectiveness using risk information

- RS-MS1-3 Assessment Process
- RS-MS3-2 Industry Trends Support
- RS-MS3-3 Reactor Performance Data Collection
- RS-MS3-4 ASP Analyses

RS-EER1-8 Develop a regulatory guide and accompanying SRP chapter providing an approach for assessing the adequacy of PRA results used in support of regulatory applications.

- RS-MS5-1 RG 1.174 and SRP 19
- RS-MS5-3 Licensing Basis Changes: Inservice Inspection
- RS-MS5-4 Licensing Basis Changes: Inservice Testing
- RS-MS5-5 Licensing Basis Changes: Technical Specifications
- RS-MS5-6 Licensing Basis Changes: Non Risk-Informed Guidance
- RS-MS8-1 Special Treatment Requirements
- RS-MS8-4 Additional Changes to Part 50
- RS-EER1-2 PRA Standards Development
- RS-EER1-3 Improved Methods of Calculating Risk
- RS-EER1-4 Fire Safety Methods
- RS-EER1-5 Maintain Analytical Tools
- RS-MS3-6 SPAR Models
- MS-EER1-1 Risk-Informing NMSS Regulatory Process
- WS-MS1-1 Dry Cask PRA

Wastes and Materials Arenas

MS-EER1-1 Develop a Framework for Incorporating Risk Information in the NMSS Regulatory Process

- MS-MS1-1 Fuel Cycle Oversight Program
- MS-EER1-2 NMSS Risk Training Program
- MS-EER1-3 Develop a Guide for Performing Risk Analyses

- MS-EER1-4 Develop Safety Goals for Materials and Waste Arenas
- WS-EER1-1 Cross-cutting Risk Assessment of Spent Fuel Management
- RS-MS1-1 Reactor Oversight Process
- RS-MS5-1 RG 1.174 and SRP 19
- RS-EER1-2 PRA Standards Development
- RS-EER1-8 PRA Adequacy Reg Guide

***MS-EER1-2* Develop Training Program to Support a Risk-Informed Approach to Implementing NMSS Regulatory Activities**

- MS-EER1-1 Risk-Informing NMSS Regulatory Process
- MS-EER1-3 Develop a Guide for Performing Risk Analyses
- MS-EER2-1 Multi-Phase Review of Byproduct Materials Program

***MS-EER1-3* Develop a Guide for Performing Risk Analyses**

- MS-EER1-1 Risk-Informing NMSS Regulatory Process
- MS-EER1-2 NMSS Risk Training Program

***MS-EER1-4* Develop Safety Goals for the Materials and Waste Arenas**

- MS-EER1-1 Risk-Informing NMSS Regulatory Process
- WS-EER1-1 Cross-cutting Risk Assessment of Spent Fuel Management

***MS-EER1-5* Interagency Jurisdictional Working Group Evaluating the Regulation of Low-level Source Material or Materials Containing less than 0.05 Percent by Weight Concentration Uranium and/or Thorium**

- No cross-cutting activities identified.

***MS-EER2-1* Multi-phase Review of the Byproduct Materials Program**

- MS-MS2-1 Materials Licensing Guidance
- MS-EER1-2 NMSS Risk Training Program

***MS-MS1-1* Revise Fuel Cycle Oversight Program**

- RS-MS1-1 Reactor Oversight Process
- MS-MS2-3 Implementation of Part 70 Revision
- MS-EER1-1 Risk-Informing NMSS Regulatory Process

***MS-MS1-2* Revise Part 72 - Geological and Seismological Characteristics for the Siting and Design of Dry Cask ISFSIs**

- WS-MS1-1 Dry Cask PRA

***MS-MS1-3* Exemptions from Licensing and Distribution of Byproduct Material; Licensing and Reporting Requirements**

- No cross-cutting activities identified.

MS-MS1-4 Amend Part 63 to Define a Quantitative Limit, in Terms of Probability of Occurrence, for Unlikely Features, Events, and Processes

- *WS-MS1-3* Incorporate Risk Information into the High-Level Waste Regulatory Framework

MS-MS2-1 Materials Licensing Guidance Consolidation and Revision

- *MS-EER2-1* Review of Byproduct Materials Program

MS-MS2-3 Implementation of Part 70 Revision

- *MS-MS1-1* Fuel Cycle Oversight Program

MS-RB1-1 Revise Part 36: Panoramic Irradiators (PRM-36-01)

- No cross-cutting activities identified.

MS-RB1-2 Revise Part 34: Radiography (PRM-34-05)

- No cross-cutting activities identified.

WS-MS1-1 Probabilistic Risk Assessment of Dry Cask Storage Systems

- *WS-EER1-1* Cross-cutting Risk Assessment of Spent Fuel Management
- *MS-MS1-2* Revise Part 72: Siting/Design of Dry Cask ISFSIs
- *RS-EER1-3* Improved Methods of Calculating Risk
- *RS-EER1-4* Fire Safety Methods
- *RS-EER1-5* Maintain Analytical Tools
- *RS-EER1-8* PRA Adequacy Reg Guide

WS-MS1-2 Incorporate Risk Information into the Decommissioning Regulatory Framework

- *RS-MS5-1* RG 1.174 and SRP 19
- *RS-MS8-7* Safeguards

WS-MS1-3 Incorporate Risk Information into the High-Level Waste Regulatory Framework

- *RS-MS5-1* RG 1.174 and SRP 19
- *MS-MS1-4* Amend Part 63
- *WS-EER1-1* Cross-cutting Risk Assessment of Spent Fuel Management

WS-EER1-1 Cross-Cutting Risk Assessment of Spent Fuel Management

- *MS-EER1-1* Risk-Informing NMSS Regulatory Process
- *MS-EER1-4* Develop Safety Goals for Materials and Waste Arenas
- *WS-MS1-1* Probabilistic Risk Assessment of Dry Cask Storage Systems
- *WS-MS1-3* Incorporate Risk Information into the High-Level Waste Regulatory Framework

Activity title and RIRIP activity identifier, which relates the activity to the Agency's strategic arenas, performance goals, and strategies described in the NRC Strategic Plan (NUREG-1614). *

Related Agency performance goals and associated strategies.

Lead and support organization

Schedule date provided when the milestone first appeared in the RIRIP.

Project considerations may include relationships to other activities and organizational entities, critical path items, special training and communication requirements, and special resource requirements.

RS-MSB-8 Reactor Safety Arena

Implementation Activity: Develop the technical basis to revise the PTS (i.e., (RES) *Maintain safety, protection of the environment, accident common defense and security*)

Primary Performance Goal: *Maintain safety, protection of the environment, accident common defense and security*

Strategy 8: *We will continue to develop and incrementally use risk-informed and, where appropriate, less prescriptive performance-based regulatory approaches to maintain safety.*

The staff is working to develop the technical basis to improve the current evaluations of reactor pressure vessel (RPV) integrity to support the current approach to the regulations associated with RPV integrity. The staff is evaluating the current approach to RPV integrity, mechanics concepts to the revision of the regulations. The staff is also performing research and analysis needed to develop a staff and licensee in performing probabilistic fracture evaluations of reactor vessel welds. In addition, the staff is performing an experimental program and a technical approach to support decisionmaking for PTS and guidance for reactor vessel embrittlement. The staff is addressing issues associated with RPV documents and in modifying the current approach to the regulations. The staff is also addressing issues associated with the current approach to the regulations. The staff is also addressing issues associated with the current approach to the regulations.

Some specific staff activities include:

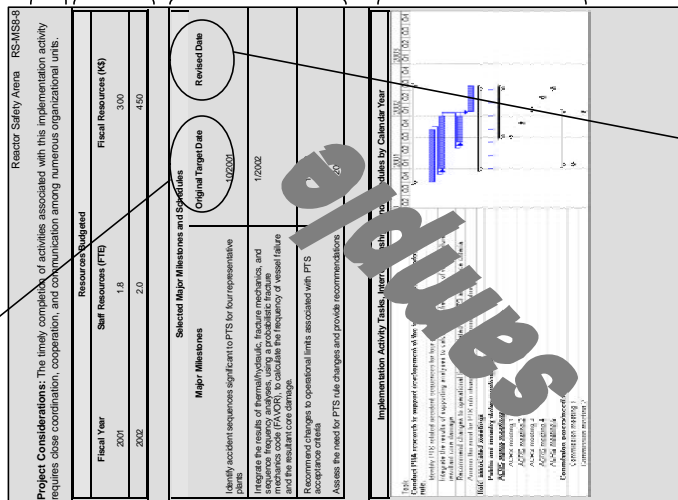
- Reviewing and updating the current approach to the regulations.
- Performing research and analysis needed to develop a staff and licensee in performing probabilistic fracture evaluations of reactor vessel welds.
- Performing an experimental program and a technical approach to support decisionmaking for PTS and guidance for reactor vessel embrittlement.
- Addressing issues associated with RPV documents and in modifying the current approach to the regulations.
- Addressing issues associated with the current approach to the regulations.

RES Priority: 8:4

Activity description

Priority assigned by lead and supporting program offices through the Planning, Budgeting, and Performance Management (PBPM) process

*The first two letters of the activity identifier indicate the relevant strategic arena (RS for reactor safety, MS for materials safety, WS for waste safety). The remaining letters and the first number indicate the Agency performance goal (MS: maintain safety; PC: public confidence; EER: effectiveness, efficiency, and realism; RB: reduce unnecessary regulatory burden) and the particular strategy to which the activity is primarily related. The last number of the activity identifier is unique to the particular activity.



Allocated resources to conduct the activity.

Major milestones and schedules.

Detailed schedule consistent with operating plans maintained by individual program offices.

Staff's current best estimated completion date.

Figure 1
Layout and Format of Activity Descriptions

Chapter 1. Reactor Safety Arena

William Kane, Arena Manager

1.1 INTRODUCTION

The NRC has generally regulated nuclear reactors based on deterministic approaches. Deterministic approaches to regulation consider a set of challenges to safety and determine how those challenges should be mitigated. As discussed in Part 1 and in the Commission's PRA Policy Statement, a probabilistic approach to regulation enhances and extends this traditional, deterministic approach by (1) allowing consideration of a broader set of potential challenges to safety, (2) providing a logical means for prioritizing these challenges based on risk significance, and (3) allowing consideration of a broader set of resources to defend against these challenges.

Until the accident at Three Mile Island (TMI) in 1979, the NRC (formerly the Atomic Energy Commission) only used probabilistic criteria in certain specialized areas of reactor licensing reviews. For example, human-made hazards (e.g., nearby hazardous materials and aircraft) and natural hazards (e.g., tornadoes, floods, and earthquakes) were typically addressed in terms of probabilistic arguments and initiating frequencies to assess site suitability. The Standard Review Plan (NUREG-0800) for licensing reactors and some of the Regulatory Guides supporting NUREG-0800 provided review and evaluation guidance with respect to these probabilistic considerations.

The TMI accident substantially changed the character of the analysis of severe accidents worldwide. It led to a substantial research program on severe accident phenomenology. In addition, both major investigations of the accident (the Kemeny and Rogovin studies) recommended that PRA techniques be used more widely to augment the traditional non-probabilistic methods of analyzing nuclear plant safety. In 1984, the NRC completed a study (NUREG-1050) that addressed the state-of-the-art in risk analysis techniques.

In early 1991, the NRC published NUREG-1150, "Severe Accident Risks: An Assessment for Five U.S. Nuclear Power Plants." In NUREG-1150, the NRC used improved PRA techniques to assess the risk associated with five nuclear power plants. This study was a significant turning point in the use of risk-based concepts in the regulatory process and enabled the Commission to greatly improve its methods for assessing containment performance after core damage and accident progression. The methods developed for and results from these studies provided a valuable foundation in quantitative risk techniques.

For the last several years, NRC's work to expand the use of PRA in regulatory processes has been documented in the PRA Implementation Plan (See SECY-99-211). Many of the early actions focused upon the development of skills, tools, and infrastructure for the application of risk information.

Reactor Safety Arena

In considering what areas in the reactor safety arena to target for greater use of risk information, the NRC staff examined the sources of risk, the existing regulatory processes, and where there were the best opportunities for improvements. This led to a focus on reactors operating at power, but also gave consideration to (1) low power and shutdown conditions, (2) reactors undergoing decommissioning with fuel stored in pools (discussed under the nuclear waste arena), and (3) advanced reactor designs.

The evolution of the staff's application of risk information to the regulation of nuclear reactors is briefly discussed below. Detailed information on specific staff activities, as it is associated with the Commission's Strategic Plan, is provided later in this chapter.

One of the first examples of the agency's efforts to risk-inform reactor regulation are the Appendices in 10 CFR Part 52 certifying the evolutionary standardized reactor designs. Part 52 requires that a PRA be performed for any future design and also that the design meet certain technical requirements to prevent and mitigate severe accidents. A rulemaking in the planning stage would further require that operators of standard design plants maintain a "living" PRA.

SECY-97-171 (Consideration of Severe Accident Risk in NRC Regulatory Decisions) discussed how severe accident risk had been considered in the past as well as areas where it might be for the future. For instance, the NRC promulgated new rules requiring plants to deal with accidents that were beyond the normal design basis (station blackout and anticipated transients without scram) on the basis of risk information. The regulatory analysis guidelines by which NRC makes decisions about whether requirements are cost-beneficial backfits also consider risk of severe accidents. As discussed in Part 1, the development of the Safety Goal Policy was also a major step. Beginning in 1988, the staff also undertook a plan to consider severe accident risks for existing plants. This plan included several activities, including issuance of a Generic Letter (GL 88-20) asking licensees to conduct Individual Plant Examinations (IPEs) to look for plant-specific vulnerabilities to severe accidents. Other activities considered containment performance and utility severe accident management programs.

With the enhanced capabilities to assess risk, the staff also recognized that there were opportunities to reduce unnecessary regulatory burden. Stakeholder input was sought to identify areas that presented burden and in which risk information indicated that the burden may not be commensurate with the risks. Initial efforts focused on discrete areas to gain experience with use of the tools and guidance. As noted, the staff first developed the basic guiding principles (safety goal, PRA policy, and general guidance for licensing action decisions) and then proceeded with pilot applications. Over the last several years, the staff has reviewed individual licensing actions in such areas as graded quality assurance, in-service inspection, in-service testing, or changes to allowed outage times in the technical specifications. Having completed several pilots, the staff has concluded that greater use of risk information in the regulatory process could be accomplished in a manner that maintained safety, improved safety focus, and reduced unnecessary burden. Thus, the staff is now focusing upon other activities, such as rulemaking, to offer voluntary options for licensees. These activities include both specific technical areas (e.g., fire protection) as well as broader changes such as the adjustment of special treatment requirements.

It should be noted that, where necessary, the staff has also added requirements as a result of risk information. For example, the maintenance rule (10 CFR 50.65) was recently modified to require licensees to assess and manage the increase in risk that may result from maintenance activities.

Reactor Safety Arena

Risk information is being used to focus staff activities with respect to inspection and enforcement and to adjust specific requirements on licensees. For example, the risk-informed oversight effort was developed using the results of research work and previous risk studies to identify the most significant systems, structures and components and to develop processes by which the risk significance of inspection findings could be determined. For instance, in judging the areas and the amount of inspection effort to apply, the risk significance of the activities or systems involved was considered. Further, risk information was used where possible in setting the thresholds for the performance indicators. When judging the importance of inspection findings, the significance determination process uses risk information to assess the significance of the issue. These assessments are then input to an assessment process to define the agency response, depending upon both the significance of individual findings as well as overall plant performance.

The staff has also been using risk information for several years for event assessment. For example, the accident sequence precursor program determines conditional core damage probability for particular events or plant conditions. Finally, the staff is continuing activities to enhance its capabilities to conduct or review risk analyses through various research programs. These include activities to improve tools, enhance data, and to identify areas where requirements can be adjusted in a risk-informed manner.

Prioritization of Reactor Safety Arena RIRIP Implementation Activities

In response to the Commission's direction in the January 4, 2001, SRM on the October 2000 version of the RIRIP, the priority rating(s) is listed under each implementation activity. The prioritization processes followed by NRR and RES management, although not the same, use the agency's strategic plan performance goals to prioritize Office activities as part of the budget process. The RES prioritization scores range from 1-10, with 10 indicating highest priority. NRR prioritization scores range from 1-12, with 12 indicating highest priority. Because the scoring systems are not intended to numerically order the activities, it is important to note that more than one activity may have the same score. Staff activities are prioritized as they relate to: maintaining safety; improving effectiveness, efficiency, and realism; reducing unnecessary regulatory burden; and increasing public confidence. As with other staff activities, changes in priorities of the staff's risk-informed regulation implementation activities will continue to be made consistent with the PBPM process to reflect changes to the agency budget and priorities.

Plan for Improving Coherence Among Reactor Arena Risk-Informed Activities

Although a great deal of progress has been made towards risk-informing regulatory activities, the staff is aware that many existing regulations remain inconsistent (or incoherent) with risk-informed practices. Many NRC regulations and processes have evolved in a less-than-integrated manner over the years. For example, the risk-informed significance determination processes used to evaluate performance deficiencies under the current reactor oversight program (ROP) have identified numerous regulations for which non-compliance is not risk-significant. In addition, since risk was not assessed when most reactor design basis regulations were promulgated, use of the risk-informed ROP emphasizes safety issues not directly addressed in licensee Final Safety

Analysis Reports or other docketed material. Furthermore, research and analysis over the years has revealed that some NRC regulations are overly conservative or unnecessarily burdensome without commensurate benefits to public safety. These regulations divert licensee and NRC resources away from more safety significant issues.

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There may also be inconsistencies between the approaches and the objectives that the staff has used to risk-inform different activities.

Consequently, the staff has been developing a program to address the coherence of regulatory activities. This program would provide an approach in which the reactor regulations, staff programs, and processes are built on a unified safety concept and are properly integrated so that they complement one another. An inter-office working group has been formed and is developing a detailed action plan for the program to improve coherence among risk-informed activities. The staff intends to engage stakeholders throughout the process.

Responding to a briefing by the staff on significant issues in the reactor safety arena, the Commission stated in a February 8, 2002, SRM that, in parallel to these staff activities, "in the next version of the RIRIP, the staff should provide its plan for moving forward with risk-informed regulation to address regulatory structure convergence with our risk-informed processes."

To complete this initiative, the staff will continue to investigate why there is not a common understanding of risk-informed regulatory objectives. Next, the staff will develop an overarching approach to provide a common structure for risk-informing activities. This approach will be based on the framework previously developed for risk-informing Part 50 that was presented in SECY-00-0198 ("Status Report on Study of Risk-Informed Changes to the Technical Requirements of 10 CFR Part 50 (Option 3) and Recommendations on Risk-Informed Changes to 10 CFR 50.44 (Combustible Gas Control)," dated September 14, 2000). The overarching approach will also utilize and expand the cornerstones developed by the reactor oversight program. The staff will use stakeholder input (such as NEI-02-02, "A Risk-Informed, Performance-Based Regulatory Framework for Power Reactors," dated May 2002, and related work now being funded by the Department of Energy) and will also solicit additional input.

Next, the staff will determine the desired characteristics of an integrated, risk-informed regulatory structure. These characteristics will be derived from the characteristics defined in SECY-98-300, "Options for Risk-Informed Revisions to 10 CFR Part 50 – 'Domestic Licensing of Production and Utilization Facilities'," dated December 23, 1998, and will be consistent with the philosophy outlined in the Commission White Paper on Risk-Informed, Performance-Based Regulation, dated March 11, 1999.

The staff then will evaluate risk-informed activities to identify inconsistencies and commonalities among activities and their desired characteristics, as noted above. We will look for safety concerns, inefficiencies, and unnecessary regulatory burden. Based on the results of the evaluation, we will set priorities and modify activities, as appropriate, so that they meet the desired characteristics. It should be noted that legitimate differences may exist among activities due to their particular purpose but that the activities should each contribute to the overarching goal of risk-informed regulation.

As noted above, the staff intends to engage stakeholders throughout the process. The detailed plan includes numerous public meetings and workshops. We will provide more details on the program to the Commission in a separate paper this fall. The staff anticipates that this paper will include a summary of its initial meetings with stakeholders and its thoughts on standardizing the terminology used in risk-informed applications and a common objective for the program.

In parallel with work to risk-inform operating reactor regulatory processes, the staff has been investigating approaches for making advanced reactor licensing more risk-informed. One part

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of the staff's program to improve coherence will be an assessment of whether merging this advanced reactor framework development with operating reactor process improvements will result in a more efficient and effective outcome. It is not yet clear that this will be the case because of a number of policy and technical issues unique to some advanced reactor design reviews. However, the staff is starting with the idea that a single, top-down approach is best, where differences between advanced reactors and operating reactors are addressed at a lower level in the framework. Some of these policy issues (e. g., whether current risk metrics are sufficient for all advanced reactor designs) are the subject of a separate Commission paper now being written.

1.2. DESCRIPTION OF CURRENT INITIATIVES AND ACTIVITIES

Current initiatives and activities to risk-inform the regulatory applications of the reactor safety arena include the following:

- RS-MS1-1 Establish a framework for deciding on inspection, assessment, and enforcement action for nuclear power reactors that focuses on activities and systems that are risk-significant
- RS-MS1-2 Risk-inform the baseline inspection program for all nuclear power plants with additional inspections that may be performed in response to a specific event or problem at a plant.
- RS-MS1-3 Maintain a risk-informed assessment process for determining NRC actions based upon performance indicator and inspection information
- RS-MS3-1 Reactor Oversight Process Support
- RS-MS3-2 Industry Trends Support
- RS-MS3-3 Reactor Performance Data Collection Program
- RS-MS3-4 Accident Sequence Precursor Analysis Program
- RS-MS3-5 Review IPEEE submittals and issue insights report
- RS-MS3-6 SPAR Model Development Program
- RS-MS5-1 Establish guidance for risk-informed licensing basis changes: Update Regulatory Guide 1.174 and SRP Chapter 19

- RS-MS5-2 Establish application-specific guidance for risk-informed licensing basis changes: Updating the Graded QA RG
- RS-MS5-3 Establish application-specific guidance for risk-informed licensing basis changes: Risk-Informed Inservice Inspection
- RS-MS5-4 Establish application-specific guidance for risk-informed licensing basis changes: Inservice Testing

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- RS-MS5-5 Establish application-specific guidance for risk-informed licensing basis changes: Technical Specifications
- RS-MS5-6 Establish guidance for risk-informed licensing basis changes: guidance for use when reviewing non-risk-informed submittals
- RS-MS8-1 Develop an alternative risk-informed approach to special treatment requirements in Part 50 that would vary the treatment applied to structures, systems and components (SSC) on the basis of their safety significance using a risk-informed categorization method
- RS-MS8-2 Change technical requirements of 10 CFR 50.44 (“Standards for Combustible Gas Control in Light-Water-Cooled Power Reactors”)
- RS-MS8-3 Change technical requirements of 10 CFR 50.46 (“Acceptance Criteria for Emergency Core Cooling Systems for Light-Water Nuclear Power Reactors”)
- RS-MS8-4 Evaluate the feasibility of additional changes to the technical requirements of 10 CFR Part 50
- RS-MS8-5 Develop risk-informed improvements to the standard technical specifications (STS)
- RS-MS8-6 Fire protection for nuclear power plants
- RS-MS8-7 Develop alternative requirements for safeguards that are risk-informed and/or performance-based
- RS-MS8-8 Develop the technical basis to revise the PTS rule
- RS-MS8-9 Develop the technical basis to support risk-informed review of advanced reactors
- RS-MS8-10 Develop methods for assessing steam generator performance during severe accidents
- RS-EER1-1 Creating a risk-informed environment

- RS-EER1-2 Develop standards for the application of risk-informed, performance-based regulation in conjunction with national standards committees
- RS-EER1-3 Develop improved methods for calculating risk in support of risk-informed regulatory decision making
- RS-EER1-4 Develop and apply methods for assessing fire safety in nuclear facilities
- RS-EER1-5 Develop and maintain analytical tools for staff risk applications
- RS-EER1-7 Assess regulatory effectiveness using risk information

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- RS-EER1-8 Develop a regulatory guide and accompanying SRP chapter providing an approach for assessing the adequacy of PRA results used in support of regulatory applications.

These initiatives and activities are described in detail on the following pages. The descriptions include applicable project considerations, such as priority, resource allocation, schedule and milestone, interrelationships among activities, and special considerations (e.g., training, stakeholder communications, external dependencies).

Implementation Activity: Establish a framework for deciding on inspection, assessment and enforcement actions for nuclear power reactors that focuses on activities and systems that are risk-significant. (NRR)

Primary Performance Goal: *Maintain safety, protection of the environment, and the common defense and security*

Strategy 1: *We will sharpen our focus on safety to include a transition to a revised NRC reactor oversight program for our inspection, assessment, and enforcement activities.*

Secondary Performance Goal: *Reduce unnecessary regulatory burden on stakeholders*

Strategy 3: *We will improve our reactor oversight program by redirecting resources from those areas less important to safety.*

The basic approach under the new oversight process is to monitor performance with respect to reactor safety cornerstones (initiating events, mitigation system performance, barrier integrity, and emergency preparedness), radiation safety (worker exposure and general public protection during routine operations), and security. Indicators that can be used to monitor performance against these cornerstones have been developed. NRC has also identified "inspectable areas" which relate to these cornerstones and for which performance indicators alone are not sufficient to monitor performance. NRC is also inspecting the performance indicator reporting process. Results and lessons learned from the first year of implementation of the new reactor oversight process are documented in SECY-01-0114 dated June 26, 2001 and, for the second cycle, in SECY-02-0062 dated April 3, 2002.

NRR Priority: 11

Project Considerations: The revised process was developed with input from a wide range of stakeholders. It was piloted with a subset of the reactors and the new program was implemented nationwide in April 2000. Lessons learned will be shared with NMSS in its efforts to improve the materials and waste regulatory framework.

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2001	30.7	0
2002	31.7	0

Selected Major Milestones and Schedules			
Major Milestones	Original Target Date	Revised Date	Completion Date
Report on lessons learned from full implementation	June 2001		June 2001
Status report on lessons learned from implementation	March 2002		April 2002
Annual status report on ROP implementation	March 2003		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year																				
Task	2001				2002				2003				2004				2005			
	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	
Monitor implementation of reactor oversight process.																				

Implementation Activity: Risk-inform the baseline inspection program for all nuclear power plants with additional inspections that may be performed in response to a specific event or problem at a plant. (NRR)

Primary Performance Goal: *Maintain safety, protection of the environment, and the common defense and security*

Strategy 1: *We will sharpen our focus on safety to include a transition to a revised NRC reactor oversight program for our inspection, assessment, and enforcement activities.*

Secondary Performance Goal: *Reduce unnecessary regulatory burden on stakeholders*

Strategy 3: *We will improve our reactor oversight program by redirecting resources from those areas less important to safety.*

The risk-informed oversight effort was developed using the results of research work and previous risk studies to identify the most significant systems, structures and components (risk matrices) and to develop processes by which the risk significance of inspection findings could be determined (significance determination process). For instance, in judging the areas and the amount of inspection effort to apply, the risk significance of the activities or systems involved was considered. Also, the staff used the results of previous experiences to ascertain how we have used risk significant issues in the past.

NRR Priority: 11

Project Considerations: The staff developed a self-assessment process to continue to refine and improve the reactor oversight process to incorporate lessons learned and future risk insights.

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2001	3.0	0
2002	2.0	0

Selected Major Milestones and Schedules			
Major Milestones	Original Target Date	Revised Date	Completion Date
Revise inspection procedures to incorporate lessons learned from initial implementation	January 2002		January 2002
Quarterly inspection procedure updates to incorporate lessons learned from ROP implementation	January 2003		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year													
Task	2000				2001				2002				2003
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1
Monitor and improve the baseline inspection program.													

Implementation Activity: **Maintain a risk-informed assessment process for determining NRC actions based upon performance indicator and inspection information. (NRR)**

Primary Performance Goal: *Maintain safety, protection of the environment, and the common defense and security*

Strategy 1: *We will sharpen our focus on safety to include a transition to a revised NRC reactor oversight program for our inspection, assessment, and enforcement activities.*

Secondary Performance Goal: *Reduce unnecessary regulatory burden on stakeholders*

Strategy 3: *We will improve our reactor oversight program by redirecting resources from those areas less important to safety.*

The assessment process utilizes inspection and performance indicator results. Risk information is used where possible in setting the thresholds for the performance indicators. When judging the importance of inspection findings, the significance determination process uses risk information to assess the significance of the issue. These assessments are then input to an assessment process (action matrix) to define the agency response, depending upon both the significance of individual findings as well as overall cornerstone performance. The notebooks used for the SDP will be improved in order to address challenges identified with the implementation of the SDP. The staff has developed SDP improvement strategies and an associated SDP Improvement Task Action Plan to provide for continued improvements in the timeliness, consistency, and usefulness of the SDP tools.

Performance is assessed by categorizing the indicators and inspection findings using significance thresholds to decide upon agency response. Depending upon the results in the various cornerstone areas, NRC will continue its baseline inspection, will inspect licensee corrective actions to deal with problem areas, will undertake additional inspections to focus upon the cause of the degraded performance, or if performance is unacceptable, the plant will not be permitted to operate until the problems are corrected.

NRR Priority: 11

Project Considerations: The NRC has convened a task group to assess inspector training and qualifications in light of the new reactor oversight program and other risk-informed initiatives. The task group consists of representatives from NRR, HR and the regions. The task group began meeting in July and August 2000 to plan its review.

Performance indicator information, inspection findings, and the results of the NRC assessment process are made publicly available through the NRC web site, enhancing communication with licensees and the public. The staff is working with the industry to make PRA results and risk information more available to the public. The staff will continue to evaluate the ROP for lessons learned through a periodic self-assessment process.

The risk-based performance indicators currently under development will reflect risk-significant changes in plant performance and will be used in the assessment process. Likewise, SPAR models support Phase 3 of the significance determination process.

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2001	4.6	215
2002	4.7	300

Selected Major Milestones and Schedules			
Major Milestones	Original Target Date	Revised Date	Completion Date
Maintain and improve significance determination process notebooks	September 2001	October 2004	

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year																
Task	2000				2001				2002				2003			
	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	
Provide technical support in risk-informing the assessment process.																

Implementation Activity: Reactor Oversight Process (ROP) Support (RES)

Primary Performance Goal: *Maintain safety, protection of the environment, and the common defense and security*

Strategy 3: *We will evaluate operating experience and the results of risk assessments for safety implications.*

Under Reactor Oversight Process support, RES:

- ▶ Compares ASP and SDP findings in support of ROP.
- ▶ Transfers shutdown Risk-Based Performance Indicator (RBI) results and insights to NRR to enhance SDP.
- ▶ Develops plant-specific thresholds for unreliability and unavailability PIs for pilot plants using available Rev 3 SPAR models.

Reactor Oversight Process information is used by NRR/DIPM/IIPB to:

- ▶ Compare ASP and SDP findings.
- ▶ Enhance shutdown SDP by using shutdown RBI results and insights.
- ▶ Evaluate the unreliability and unavailability PIs based on plant-specific thresholds that were developed using available Rev 3 SPAR models.

RES Priority: 6.2

NRR Priority: 6.0

Project Considerations: Continued availability of databases containing equipment reliability and availability data is necessary for the development and reporting of RBPIs. The RBPIs will utilize information obtained from: (1) inspection reports and Standardized Plant Analysis Risk (SPAR) models; (2) industry-wide analyses reported via initiating event studies, component reliability studies, system reliability studies, common-cause failure (CCF) studies, and special issue studies such as those addressing fire events and service water system events; and (3) operational data contained in the Sequence Coding and Search System (SCSS) Licensee Event Report (LER) database, the Reliability and Availability Data System (RADS), the CCF database, and the Monthly Operating Report (MOR) database.

RBPIs will support the ROP assessment activities by providing direct measurements of the performance of risk-important safety features to determine whether safety is improving, deteriorating, or remaining constant. The supporting analyses and data systems needed to develop RBPIs will also be used by NRR’s inspection staff in developing risk-informed inspection guidance and significance determination process (SDP) evaluations, and by RES staff that use risk-important information to identify ways to improve the effectiveness of NRC regulatory requirements, guidance, and processes.

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2002	2.0	641

Selected Major Milestones and Schedules			
Major Milestones	Original Target Date	Revised Date	Completion Date
Provide quarterly-update reports on comparison of ASP and SDP findings in support of ROP.	June 2002; September 2002; December 2002; March /2003		
Draft guidance document for unreliability computation to support July 2002 PI pilot program public workshop.	June 2002		
Pilot Plants — Determine plant-specific thresholds for the unreliability and unavailability indicators using available Rev 3 SPAR models.	September 2002		
Provide pilot program support, including input to NRR Regulatory Information Summary	September 2002		
For all plants — Determine plant-specific thresholds for the pilot program unreliability and unavailability indicators and prepare preliminary report.	September 2002		
Prepare guidance document for technology transfer of RBPIs for shutdown to the NRR staff to enhance shutdown SDP.	September 2002		
Prepare internal report on feasibility of developing containment PIs using SPAR models for LERF.	September 2002		
Perform and document a feasibility study to develop PIs at higher levels.	September 2002		

Implementation Activity: Industry Trends Support (RES)

Primary Performance Goal: *Maintain safety, protection of the environment, and the common defense and security*

Strategy 3: *We will evaluate operating experience and the results of risk assessments for safety implications.*

Industry Trends Support:

- ▶ Provides trends for initiating events, systems reliability, components reliability, common-cause failures, and fire events
- ▶ Develops thresholds for the above trends for use in a risk-informed regulatory framework.
- ▶ Provides reactor operating experience information on systems, components, initiating events, CCF events, and fire events.

Industry Trends are used by:

- ▶ NRR/DIPM/IIPB to: (1) monitor trends and report results to Congress; (2) monitor industry-wide safety performance and provide feedback to the ROP; and (3) enhance plant inspections of risk-important systems.
- ▶ NRR/DSSA/SPSB to support risk-informed technical reviews of proposed license amendments.
- ▶ RES/DSARE/REAHFB to evaluate the effectiveness of regulatory requirements.

Planned Efficiencies

- ▶ NUREG/CR and NUREG reports were prepared periodically for systems, initiating events, components, and common-cause failures (21 reports in all). The production of these reports has been stopped. Approximately 20 different reports have been produced and updated in the past. The results were not timely nor up to date. Each report costs approximately \$40,000 to produce, print, and distribute. The reports are continuing to be updated but the results will be made available on the NRC Web site. This will allow for easier and more timely dissemination of material at a much lower cost.

RES Priority: 6.0

Project Considerations: Continued availability of databases containing equipment reliability and availability data is necessary for the development and reporting of the risk significance of industry-wide operational events and data trends, as well as for conducting system reliability and related studies. The data for these studies is contained in the SCSS LER database, RADS, the CCF database, and the MOR database.

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2002	3.5	254

Selected Major Milestones and Schedules			
Major Milestones	Original Target Date	Revised Date	Completion Date
Produce industry and plant-specific reliability, availability, CCF estimates, summary tables, graphs and/or charts for: components, systems, initiating events, CCF events; OECD/NEA ICDE support, and special requests/studies.	Ongoing		
For all plants — Co-develop plan, methodology, and draft report documenting results determining risk-informed industry trend thresholds for ASP, ROP PIs, systems, and initiating events	September 2002	September 2003	
For all plants — Using methodology developed previously, determine and document risk-informed industry trend thresholds for the system reliability, common-cause failure, fire, and component studies in NUREGs.	Ongoing		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year												
Task	2002				2003				2004			
	Qtr 4	Qtr 3	Qtr 2	Qtr 1	Qtr 4	Qtr 3	Qtr 2	Qtr 1	Qtr 4	Qtr 3	Qtr 2	Qtr 1
Industry Trends Support												
Produce industry and plant-specific reliability, availability, CCF estimates, summary tables, graphs and/or charts for: components, systems, initiating events, CCF events; OECD/NEA ICDE support and special requests/studies (ongoing).												
For all plants — Co-develop plan, methodology, and draft report documenting results determining risk-informed industry trend thresholds for ASP, ROP PIs, systems, and initiating events.												
For all plants — Using methodology developed previously, determine and document risk-informed industry trend thresholds for the system reliability, common-cause failure, fire, and component studies in NUREGs (ongoing).												
For all plants — Co-develop plan, methodology, and draft report documenting results determining risk-informed industry trend thresholds for ASP, ROP PIs, systems, and initiating events.												

Implementation Activity: Reactor Performance Data Collection Program. (RES)

Primary Performance Goal: *Maintain safety, protection of the environment, and the common defense and security*

Strategy 3: *We will evaluate operating experience and the results of risk assessments for safety implications.*

Under the Reactor Performance Data Collection Program, RES operates the following databases:

- ▶ Sequence Coding and Search System (SCSS) which contains information about events at nuclear power plants in a Web-based searchable system based on the sequence-coding of information in Licensee Event Reports (LERs).
- ▶ Reliability and Availability Data System (RADS) which estimates plant-specific and generic component-level reliability, and train level availability. RADS includes input from the Equipment Performance and Information Exchange (EPIX) database, which is maintained by the Institute of Nuclear power Operations (INPO).
- ▶ The events database which contains information that is used to update the RES reliability, availability, and initiating events studies.
- ▶ The Common-Cause Failure (CCF) database which contains data on risk-significant interactions, phenomena, and behavior in the design and operation of nuclear power reactors that originate from a common cause and were not previously recognized and analyzed.
- ▶ The Monthly Operating Report (MOR) database which contains data on plant operations that are submitted by licensees via Monthly Operating Reports.
- ▶ The Accident Sequence Precursor (ASP) Events database which contains summary information on all the ASP events since 1969.

RES also has access to the following external databases:

- ▶ INPO's EPIX database.
- ▶ The Swedish Nuclear Power Inspectorate (SKI) database maintained by the Nuclear Energy Agency of the Organization of Economic Cooperation and Development (OECD/NEA).

Planned Efficiency for the Reactor Performance Data Collection Program (Starting in FY2004):

- ▶ In the past, data have been collected and coded separately for each study or activity (11 system studies, 4 components studies, initiating events study, common-cause failures). Thus the same data were read several times. Data coding will be consolidated to eliminate this inefficiency. The data will be read once and coded for all studies at one time. Another consolidation step is to integrate the coding of LERs and the data coding efforts at one location, thus eliminating duplication of efforts currently conducted at ORNL (Sequence Coding and Search System [SCSS] LER database) and INEEL.

RES Priority: 5.8

Project Considerations: The databases that are available through the RES Reactor Performance Data Collection Program are used to support:

- ▶ All RES/DRAA/OERAB analysis activities which include:
 - ▶ Plant-specific event analyses, such as ASP analyses using SPAR models.
 - ▶ Industry-wide analyses that are reported via initiating event studies, component reliability studies, system reliability studies, CCF studies, and special issue studies such as those addressing fire events and service water system events.
 - ▶ The development of Risk-Based Performance Indicators (RBPIs).
- ▶ NRR/DSSA/SPSB’s risk-informed review of submittals, SDP evaluations, and resolution of generic safety issues.
- ▶ NRR/DIPM/IIPB’s development of risk-informed inspection guidance.
- ▶ RES/DSARE/REAHFB’s identification of ways to improve the effectiveness of NRC regulatory requirements, guidance, and processes.
- ▶ NRC’s development of mitigating system PIs and associated pilot program for the ROP.

In addition, the NRC licensees have access to the CCF database.

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2002	2.5	1978

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year														
Task	2001		2002				2003				2004			
	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Reactor Performance Data Collection Program														
SCSS database (ongoing)														
RADS database (ongoing)														
CCF database (ongoing)														
MOR database (ongoing)														
EPX database access (ongoing)														
ASP database (ongoing)														

Implementation Activity: Accident sequence precursor (ASP) Program (RES)

Primary Performance Goal: *Maintain safety, protection of the environment, and the common defense and security*

Strategy 3: *We will evaluate operating experience and the results of risk assessments for safety implications.*

Under the Accident Sequence Precursor (ASP) Program, RES continues to review and evaluate operational experience to identify precursors to potential severe core damage sequences. This work includes:

- Documenting precursors.
- Categorizing precursors by plant-specific and generic implications.
- Providing a measure for trending nuclear plant core damage risk.
- Providing a partial check on failure combinations identified in PRAs and IPEs.

ASP analyses are used to support:

- Documenting Annual Performance and Accountability Report to Congress via the OCFO (significant precursors) and via NRR/DIPM/IIPB (adverse industry trend).
- Industry trends program by NRR/DIPM/IIPB.
- Annual SECY paper to the Commission on the status of the ASP program.
- Assessment by NRR/DSSA/SPSB of the risk associated with actual events to support senior management decisions to dispatch an AIT or IIT.
- NRR decisions to develop generic communications.
- Studies by RES/DSARE/REAHFB to determine the safety significance of potential regulatory issues.

RES Priority: 5.8

Project Considerations: Continued availability of databases containing equipment reliability and availability data is necessary to support the ASP program. ASP analyses utilize information obtained from: (1) inspection reports and SPAR models; (2) industry-wide analyses reported via initiating event studies, component reliability studies, system reliability studies, CCF studies, and special issue studies such as those addressing fire events and service water system events; and (3) operational data contained in the SCSS LER database, RADS, the CCF database, and the MOR database.

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2002	3.0	715

Selected Major Milestones and Schedules			
Major Milestones	Original Target Date	Revised Date	Completion Date
Issue annual SECY paper to the Commission on the ASP program	March 2002		March 2002
Issue annual SECY paper to the Commission on the ASP program	March 2003		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year												
Task	2002				2003				2004		2005	
	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	
Accident Sequence Precursor (ASP) Program												
Issue annual SECY paper to the Commission on the ASP program (FY02)		◆										
Provide DCFO with identified precursors for submittal to Congress					◆							
Provide NRR with trends for submittal to Congress via OCFD					◆							
Issue annual SECY paper to the Commission on the ASP program (FY03)						◆						
Provide DCFO with identified precursors for submittal to Congress									◆			
Provide NRR with trends for submittal to Congress via OCFD									◆			

Implementation Activity: Review IPEEE submittals and issue insights report. (RES)

Primary Performance Goal: *Maintain safety, protection of the environment, and the common defense and security*

Strategy 3: *We will evaluate operating experience and the results of risk assessments for safety implications.*

The staff completed its review of the industry's Individual Plant Examination - External Events (IPEEE) submittals. A draft insights report was issued for public comment, comments were received, the report was appropriately revised, and a final insights report was prepared. The IPEEE program was a success that resulted in the nuclear power industry identifying safety improvements that substantially reduced the risk of accidents. Over 80% of the licensees have identified and implemented or proposed plant improvements to address concerns revealed through the IPEEE program. These voluntary licensee improvements have led to enhanced plant capability to respond to external events (such as earthquakes and floods) which can be important contributors to total plant core damage frequency. The generic insights from this effort will be used to support development of PRA guidance and standards, while plant-specific risk information will support the risk-informed reactor oversight program. The IPE/IPEEE programs were formally closed out by a memorandum from A. Thadani to W. Travers, dated October 19, 2001. The IPEEE report was issued as NUREG-1742, dated April 2002. No further updates will be provided.

RES Priority: 9.6

Project Considerations: Insights derived from the IPE and IPEEE programs are being used by the staff in its review of license amendment requests and in the significance determination process used in the reactor oversight process.

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2001	4.1	515
2002	0.3	0

Activity is complete.

Implementation Activity: SPAR Model Development Program (RES)

Primary Performance Goal: *Maintain safety, protection of the environment, and the common defense and security.*

Strategy 3: *We will evaluate operating experience and the results of risk assessments for safety implications.*

Under the Standardized Plant analysis Risk (SPAR) Model Development Program, RES is developing:

- ▶ Level 1, Rev. 3 Models.
- ▶ Level 2/LERF Models.
- ▶ Low Power/Shutdown (LP/SD) Models.
- ▶ External Events Analysis Models.
- ▶ SDP Front-End Interface for SPAR Models.

SPAR models are used to:

- ▶ Promptly assess the risk significance of events to identify regulatory actions by NRR and the Regions.
- ▶ Evaluate the significance of inspection findings in SDP Phase 3 by NRR and the Regions.
- ▶ Establish plant-specific thresholds for unreliability and unavailability PIs by RES and NRR.
- ▶ Support risk-informed technical reviews of proposed license amendments by NRR/DSSA/SPSB.
- ▶ Evaluate the effectiveness of regulatory requirements by RES/DSARE/REAHFB.
- ▶ Estimate the risk associated with operational events/conditions as part of the ASP program by OERAB.
- ▶ Perform regulatory analyses to resolve generic issues by RES.
- ▶ Support decisions to issue generic communications by NRR.

RES Priority: 6.0

Project Considerations: Continued availability of databases containing equipment reliability and availability data is necessary for the SPAR models. SPAR models utilize data obtained from: (1) industry-wide analyses reported via initiating event studies, component reliability studies, system reliability studies, CCF studies, and special issue studies such as those addressing fire events and service water system events; and (2) operating experience data contained in the SCSS LER database, RADS, the CCF database, the MOR database, and the ASP Events database. In addition, SPAR models use information about plant design that is found in final safety analysis reports (FSARs), plant information books, and licensee's updated plant PRAs.

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2002	2	1641

Selected Major Milestones and Schedules			
Major Milestones	Original Target Date	Revised Date	Completion Date
Complete final Revision 3 SPAR Models	September 2002		
Complete additional QA Reviews of Revision 3 SPAR Models	September 2002		
Technical Support to Users of Revision 3 SPAR Models	Ongoing		
Develop LP/SD models for lead plants in 8 plant classes	Ongoing		
Add uncertainty analysis capability to HRA methodology; convert HRA methodology report to draft NUREG report, address LP/SD issues; revise report to address peer review comments; issue NUREG	September 2002		
Maintain existing LP/SD models	Ongoing		
Develop Integrated Plan for Producing Level 2/LERF Models	September 2002		
Produce and QA Level 2/LERF Models	Ongoing		
Maintain Existing Level 2/LERF Models	Ongoing		

Implementation Activity: **Establish guidance for risk-informed licensing basis changes: Update Regulatory Guide 1.174 and SRP Chapter 19 (RES & NRR)**

Primary Performance Goal: *Maintain safety, protection of the environment, and of the common defense and security*

Strategy 5: *We will ensure that changes to operating licenses and exemptions to regulations maintain safety and meet regulatory requirements.*

Secondary Performance Goal: *Reduce unnecessary regulatory burden on Stakeholders*

Strategy 1: *We will utilize risk information and performance-based approaches to reduce unnecessary regulatory burden.*

The PRA policy statement encourages greater use of PRA in all regulatory activities. One major activity is using PRA to support decisions to modify an individual plant's licensing basis. The staff prepared guidance documents to guide such risk-informed changes to a plant's licensing basis, as in requests for technical specification changes. The guidance describes acceptable means for assessing the nature and impact of licensing basis changes when the change request is supported by risk information. In being risk-informed, rather than solely based upon risk information, the NRC is retaining certain principles such as consistency with the defense-in-depth philosophy and maintenance of sufficient safety margins. The RG and the SRP were issued for public comment before being published.

NRC conducts periodic reviews of the Reg Guide and SRP to identify improvements. In the first revision of the documents since they were issued in July 1998, the following changes were made:

1. Risk related information may now be requested if new, unforeseen hazards emerge or prospects increase substantially for known hazards.
2. Indication was provided of on-going staff discussions on the effect of increases to fuel burnup and changes to mixed-oxide fuel on risk metrics, such as large early release frequency.
3. Inclusion of examples of risk insights in the decision-making process.

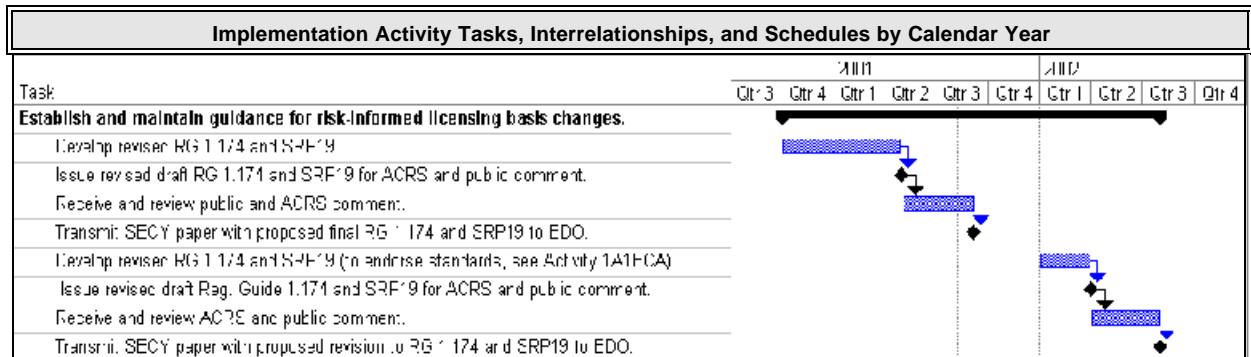
RES Priority: 8.4

NRR Priority: 6.0

Project Considerations: The staff guidance concerning risk-informed licensing basis changes is influenced by insights derived through the development of PRA standards, the development of PRA methods, and insights from IPEs, IPEEEs, and other PRAs.

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2001	<0.1 (NRR) 0.2 (RES)	0
2002	<0.1 (NRR) 0.3 (RES)	0

Selected Major Milestones and Schedules			
Major Milestones	Original Target Date	Revised Date	Completion Date
Update RG 1.174 and SRP Chapter 19	August 2001	December 2001	
Second update of RG 1.174 and SRP Chapter 19	December 2002		



Implementation Activity: Establish application-specific guidance for risk-informed licensing basis changes: Updating the Graded QA RG (NRR & RES)

Primary Performance Goal: *Maintain safety, protection of the environment, and of the common defense and security*

Strategy 5: *We will ensure that changes to operating licenses and exemptions to regulations maintain safety and meet regulatory requirements.*

Secondary Performance Goal: *Reduce unnecessary regulatory burden on Stakeholders*

Strategy 1: *We will utilize risk information and performance-based approaches to reduce unnecessary regulatory burden.*

A graded quality assurance (GQA) program was approved in 1997 for the South Texas Project (STP) as part of a GQA pilot program. The graded QA program, documented by RG 1.176, was issued in August of 1998 and reflects the lessons learned from the STP pilot review.

STP found that the benefits of the program were much less than expected. STP reported that other regulatory requirements, such as seismic, environmental qualification, and the ASME Code, imposed additional special requirements such that the expected relief was not forthcoming. Accordingly, STP submitted an application on July 13, 1999, for exemption from additional regulatory requirements. The exemption request, granted by letter dated August 3, 2001, provides the regulatory relief sought by the licensee. There have been no subsequent applications seeking to adopt a graded QA program.

The staff is using the STP exemption as a proof of concept for risk-informing the special treatment requirements of 10 CFR 50 (see RS-MS8-1). The GQA effort has been subsumed within this activity as part of the proposed rule (10 CFR 50.69). Therefore, there is no longer any need to update the status of RG 1.176. This activity is completed.

NRR Priority: NA

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2001	<0.1(NRR) <0.1 (RES)	0
2002	--	--

Activity complete.

Implementation Activity: Establish application-specific guidance for risk-informed licensing basis changes: Risk-Informed Inservice Inspection (NRR & RES)

Primary Performance Goal: *Maintain safety, protection of the environment, and of the common defense and security*

Strategy 5: *We will ensure that changes to operating licenses and exemptions to regulations maintain safety and meet regulatory requirements.*

Secondary Performance Goal: *Reduce unnecessary regulatory burden on Stakeholders*

Strategy 1: *We will utilize risk information and performance-based approaches to reduce unnecessary regulatory burden.*

The NRC issued regulatory guide 1.178 and standard review plan Section 3.9.8 in September 1998. These documents provide guidance to licensees and staff regarding risk-informed inservice inspection (RI-ISI) programs for piping systems. The staff approved two industry topical reports on RI-ISI methodology. The Westinghouse Owners Group (WOG) methodology was approved in December 1998 and the Electric Power Research Institute (EPRI) methodology was approved in October 1999.

NRC staff activities include participation in the American Society of Mechanical Engineers (ASME) code development process. In this capacity, the staff has been involved in the review of the RI-ISI code Cases N-560, N-577, and N-578 and Appendix X. Staff activities also include continuing discussions and meetings with the industry to discuss and resolve issues such as the minimum ASME Class 1 sample size and extension of the RI-ISI methodology to the break exclusion region piping.

According to the information provided by Nuclear Energy Institute (NEI), 86 plants (units) are expected to implement RI-ISI programs by the end of 2003. The NEI also indicated that of the 86 RI-ISI submittals, 61 would be based on the EPRI methodology and 25 would be based on the WOG methodology. As of the end of May 2002, 53 plants have submitted their RI-ISI programs. The staff has approved 46 programs and the remaining 7 programs are currently under review.

The staff has not commenced work to revise RG 1.178 and SRP 3.9.8 since (1) the staff and the industry are still gaining experience with the implementation of the industry methodologies and (2) the three ASME Code Cases have not been finalized to incorporate lessons learned from the application of the methodologies.

NRR Priority: 10.0

RES Priority: 8.4

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2001	<0.1(NRR) <0.1 (RES)	0
2002	<0.1(NRR) <0.1 (RES)	0

Selected Major Milestones and Schedules			
Major Milestones	Original Target Date	Revised Date	Completion Date
Issue final Inservice Inspection Regulatory Guide 1.178 and SRP Chapter 3.9.8	December 2001	December 2002	

Implementation Activity: Establish application-specific guidance for risk-informed licensing basis changes: Inservice Testing (NRR & RES)

Primary Performance Goal: *Maintain safety, protection of the environment, and of the common defense and security*

Strategy 5: *We will ensure that changes to operating licenses and exemptions to regulations maintain safety and meet regulatory requirements.*

Secondary Performance Goal: *Reduce unnecessary regulatory burden on Stakeholders*

Strategy 1: *We will utilize risk information and performance-based approaches to reduce unnecessary regulatory burden.*

The NRC staff prepared Regulatory Guide 1.175 and Section 3.9.7 to the Standard Review Plan to provide guidance for the establishment of risk-informed inservice testing (RI-IST) programs for pumps and valves at nuclear power plants. Several licensees are implementing the RI-IST program guidance in whole or in part. Additional experience regarding the application of risk insights to IST programs is being obtained by the staff. For example, the staff granted a risk-informed exemption request submitted by the licensee of the South Texas Project affecting special treatment requirements of low-risk and non-risk significant safety related nuclear components. Also, the staff is developing a proposed rule that would allow risk insights to be applied in reducing the special treatment requirements in 10 CFR Part 50 for structures, systems, and components that are categorized as being of low risk significance. In addition, the American Society of Mechanical Engineers is updating the *Code for Operation and Maintenance of Nuclear Power Plants* (OM Code) and applicable Code Cases to allow further use of risk insights in the inservice testing of pump and valves. The staff will review its current guidance for the establishment of RI-IST programs following the receipt of additional experience with these initiatives to determine appropriate updating of the RI-IST program guidance.

NRR Priority: 10.0

RES Priority: 8.4

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2001	<0.1(NRR) <0.1 (RES)	0
2002	<0.1(NRR) <0.1 (RES)	0

Selected Major Milestones and Schedules			
Major Milestones	Original Target Date	Revised Date	Completion Date
Issue revision for public comment to Inservice Testing Regulatory Guide to reflect risk-informed Part 50, Option 2 rulemaking activities and experience gained with implementation of RI-IST programs and ASME risk-informed code cases	March 2002	TBD	

Implementation Activity: Establish application-specific guidance for risk-informed licensing basis changes: Technical Specifications (NRR & RES)

Primary Performance Goal: *Maintain safety, protection of the environment, and of the common defense and security*

Strategy 5: *We will ensure that changes to operating licenses and exemptions to regulations maintain safety and meet regulatory requirements.*

Secondary Performance Goal: *Reduce unnecessary regulatory burden on Stakeholders*

Strategy 1: *We will utilize risk information and performance-based approaches to reduce unnecessary regulatory burden.*

Plant-specific licensing actions using the risk-informed guidance on technical specifications (TS) have been processed in the area of relaxations of allowed outage times for particular SSC.

Revision of Regulatory Guide 1.177 can proceed with the recent approval of Revision 1 to Regulatory Guide 1.174. The staff's activities related to risk-informing TS include several other initiatives discussed under another activity (see item RS-MS8-5).

NRR Priority: 10.0

RES Priority: 8.4

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2001	<0.1(NRR) <0.1 (RES)	0
2002	<0.1(NRR) <0.1 (RES)	0

Selected Major Milestones and Schedules			
Major Milestones	Original Target Date	Revised Date	Completion Date
Issue revision for public comment to Technical Specifications Regulatory Guide 1.177 and SRP Chapter 16.1 to reflect update of RG 1.174 and SRP Chapter 19	March 2002	September 2002	

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year														
Task	2002				2003				2004				2005	
	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Revise Technical Specifications Regulatory Guide 1.177 and SRP Chapter 16.1 to reflect update of RG1.174 and SRP Chapter 19.														

Implementation Activity: Establish guidance for risk-informed licensing basis changes: guidance for use when reviewing non-risk-informed submittals (NRR)

Primary Performance Goal: *Maintain safety, protection of the environment, and of the common defense and security*

Strategy 5: *We will ensure that changes to operating licenses and exemptions to regulations maintain safety and meet regulatory requirements.*

Secondary Performance Goal: *Reduce unnecessary regulatory burden on Stakeholders*

Strategy 1: *We will utilize risk information and performance-based approaches to reduce unnecessary regulatory burden.*

As Policy Issue 4 in SECY-98-300 (Options for Risk-Informed Revisions to 10CFR Part 50), the staff recommended developing additional guidance with respect to the use of risk-informed approaches in regulatory activities. This guidance would be used in deciding if undue risk may exist when all other regulatory requirements appear to be met. SECY-99-246 (Proposed Guidelines for Applying Risk-Informed Decisionmaking in License Amendment Reviews) proposed interim guidance for applying risk-informed decisionmaking in the review of non-risk-informed license amendment requests. Central to the process is a determination as to whether the license amendment request, if granted, could create "special circumstances" under which plant operation may pose an undue risk to public health and safety even though all other regulatory requirements appear to be satisfied. The interim guidance was disseminated to the industry via Regulatory Issue Summary 2000-7.

The NRC plans to formally issue the guidance as a new appendix to Chapter 19 of the Standard Review Plan. A draft version of the appendix was published in the Federal Register for public comment on April 10, 2000, and the NRC held a public workshop to discuss the appendix on May 16, 2000. The staff discussed the draft appendix with the Advisory Committee for Reactor Safeguards (ACRS) and with the Committee to Review Generic Requirements (CRGR) and provided a final version of the appendix to the Commission on September 26, 2000. Provisions in the guidance on Commission notification were clarified in a November 13, 2000, memorandum (COMSECY-00-0038).

In the related SRM, the Commission approved the final guidance and approved its implementation in future reviews, subject to the clarification in COMSECY-00-0038 (, i.e., the staff will notify the Commission of the first few amendments judged to create special circumstances, and thereafter will use the Risk Informed Licensing Panel to provide a recommendation to upper management on whether Commission notification is appropriate). The NRC advised the industry of the final guidance via Regulatory Issue Summary 2001-02 (January 18, 2001). The final guidance was issued to the staff in 2001. Revisions to Chapter 19 of the Standard Review Plan and Regulatory Guide 1.174 will be finalized in June 2002. Thus, this activity is completed.

NRR Priority: 10.0

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2001	<0.1	
2002	--	--

Project complete.

Implementation Activity: Develop an alternative risk-informed approach to special treatment requirements in Part 50 that would vary the treatment applied to structures, systems and components (SSC) on the basis of their safety significance using a risk-informed categorization method. (NRR)

Primary Performance Goal: *Maintain safety, protection of the environment, and the common defense and security*

Strategy 8: *We will continue to develop and incrementally use risk-informed and, where appropriate, less-prescriptive performance-based regulatory approaches to maintain safety.*

Secondary Performance Goal: *Reduce Unnecessary Regulatory Burden on stakeholders*

Strategy 1: *We will utilize risk information and performance-based approaches to reduce unnecessary regulatory burden.*

The Commission decided in 1998 to consider promulgating new regulations that would provide an alternative risk-informed approach for special treatment requirements in the current regulations for power reactors. Special treatment may be defined as current requirements imposed on structures, systems, and components that go beyond industry-established requirements for equipment classified as "commercial grade" that provide additional confidence that the equipment is capable of meeting its functional requirements under design basis conditions. These special treatment requirements include additional design considerations, qualification, change control, documentation, reporting, maintenance, testing, surveillance, and quality assurance requirements. In March 2000, the Commission invited comments, advice, and recommendations from interested parties on the contemplated approach for this rulemaking. Since September 2000, the staff has been working with industry and interested stakeholders to resolve issues associated with industry-developed guidance intended to implement the rule. The staff is currently working to develop the proposed rule language and supporting regulatory information. The staff has also interacted with industry on pilot activities to test the implementing guidance at four reactor sites.

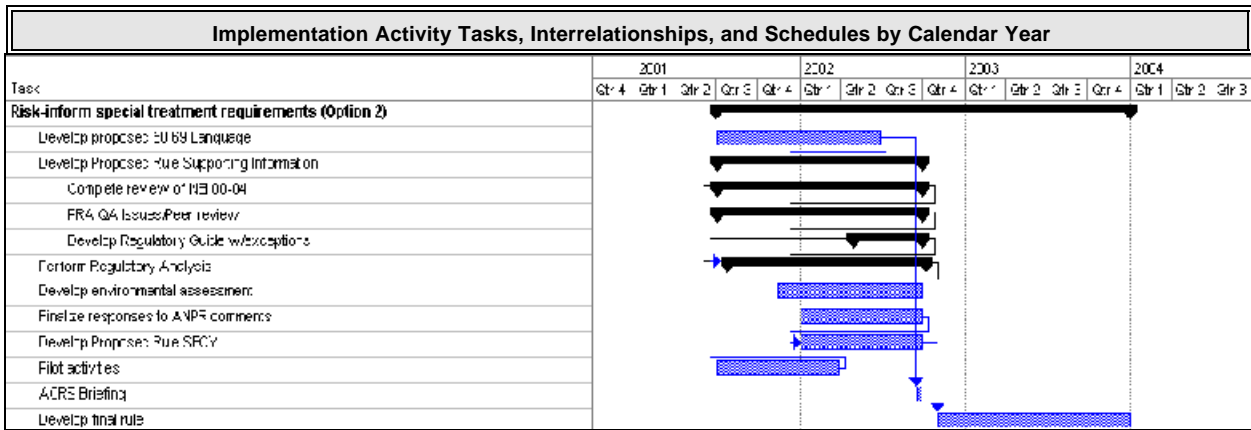
The licensee for South Texas submitted an exemption request to allow them to apply the concepts underlying this rulemaking (categorization, removal of special treatment requirements) at their facility, by receiving exemptions to certain existing requirements that would otherwise prevent them from undertaking such a program. The South Texas exemption was granted on August 3, 2001, and is considered to be a "proof-of-concept" prototype for the rulemaking. The exemption permits the licensee to implement an alternative treatment process that can result in safety-related low-risk significant (LRS) and non-risk significant (NRS) SSCs being capable of performing their safety functions under design-basis conditions throughout their service life. The staff has determined that the licensee's categorization process provides a reasonable method for determining that safety-related LRS and NRS SSCs have only a small contribution to overall safety. The experience from the licensee's efforts and the staff review is being coordinated with the rulemaking activities and guidance development. The current status of this effort is provided to the Commission on a quarterly basis; the most recent report was provided on May 13, 2002.

NRR Priority: 8

Project Considerations: The staff is currently working on developing Option 2 rule language and working with industry on NEI 00-04 implementation guidance. Challenges include translating the STP exemption lessons learned into the Option 2 framework; addressing the issue of PRA quality; and providing clear rule requirements.

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2001	3.0 (Option 2) 6.0 (STP)	12 (Option 2) 0 (STP)
2002	6.2 (Option 2)	350

Selected Major Milestones and Schedules			
Major Milestones	Original Target Date	Revised Date	Completion Date
Rulemaking			
Proposed Rule	August 2001	September 2002	
Final Rule	December 2002	December 2003	
South Texas Project Exemption (Proof of Concept)			
Draft Safety Evaluation	November 2000		November 2000
Final Safety Evaluation to Commission	April 2001		July 2001
Pilot reviews			
Complete review of owners groups' pilot IDP reviews	June 2001	October 2001	March 2002
NEI Guidance review			
Staff completes review of categorization	June 2001	July 2002	



Implementation Activity: Change technical requirements of 10 CFR 50.44 (“Standards for Combustible Gas Control in Light-Water-Cooled Power Reactors”) (NRR &RES)

Primary Performance Goal: *Maintain safety, protection of the environment, and of the common defense and security*

Strategy 8: *We will continue to develop and incrementally use risk-informed and, where appropriate, less-prescriptive performance-based regulatory approaches to maintain safety.*

Secondary Performance Goal: *Reduce unnecessary regulatory burden on stakeholders*

Strategy 1: *We will utilize risk information and performance-based approaches to reduce unnecessary regulatory burden.*

In SECY-98-300, “Options for Risk-Informed Revisions to 10 CFR Part 50 - Domestic Licensing of Production and Utilization Facilities,” dated December 23, 1998, the staff proposed three options for modifying regulations in 10 CFR Part 50 to better reflect the results of PRAs and the current understanding of reactor safety issues. The purpose of one of these options (Option 3) was to identify possible changes to specific technical requirements in Part 50, to evaluate the feasibility of such changes, and, upon approval of the Commission, to change those requirements via the NRC’s rulemaking process. The Commission approved the staff’s proposal in a June 8, 1999, Staff Requirements Memorandum (SRM). The staff provided its more detailed plan and schedule for the identification and evaluation phases of the Option 3 work in SECY-99-264, “Proposed Staff Plan for Risk-Informing Technical Requirements in 10 CFR Part 50,” dated November 8, 1999. The Commission approved proceeding with the plan in a February 3, 2000, SRM.

The staff concluded that it is feasible to change the technical requirements of 10 CFR 50.44, as discussed in SECY-00-0198, and the Commission approved making the change via the rulemaking process in a January 19, 2001, SRM. In response to the January SRM, SECY-01-0162, dated August 13, 2001, recommended revision of existing hydrogen control regulations rather than developing a voluntary alternative and the establishment of Generic Issue 189 to assess the costs and benefits of possible additional hydrogen control requirements for PER ice condenser and BWR Mark III containment designs. On December 31, 2001, the Commission approved the staff’s proposal and requested that the staff explain why installing passive autocatalytic recombiners would not pass a cost benefit test. On November 14, 2001, the staff posted draft rule language on the NRC rulemaking web site. On May 13, 2002, the staff’s proposed rule package (SECY-02-0080) was provided to the Commission.

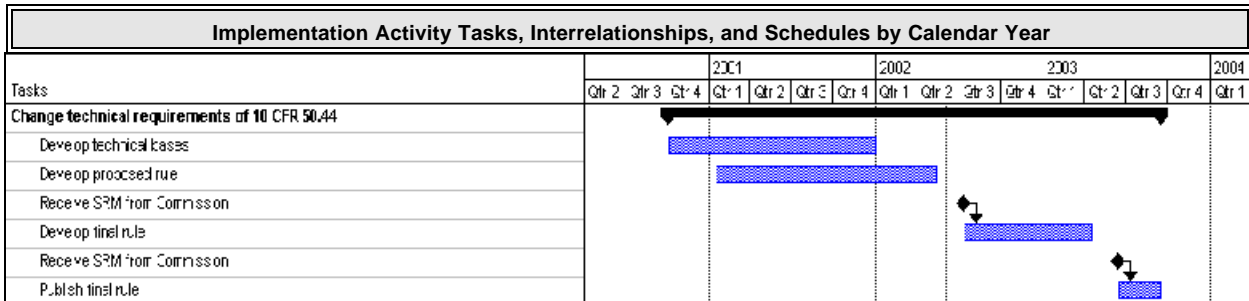
RES Priority: 8.4

NRR Priority: 8.0

Project Considerations: As the first rule using the framework document developed for identifying and assessing candidate Part 50 changes, the development of schedules and resource requirements was subject to large uncertainties. Future changes to Part 50 are expected to be more resource efficient. Nevertheless, the framework proved to be very useful to the process of risk informing 10 CFR 50.44.

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2001	1.1 (NRR) 1.0 (RES)	57 (NRR) 300 (RES)
2002	1.25 (NRR) 0.5 (RES)	40 (NRR) 200 (RES)

Selected Major Milestones and Schedules			
Major Milestones	Original RIRIP Target Date	Revised Date	Completion Date
Proposed rulemaking to change 50.44 (NRR) to Commission	January 2002	May 2002	May 2002
Final rulemaking (NRR)	6 to 9 months after SRM for proposed rule		



Implementation Activity: Change technical requirements of 10 CFR 50.46, "Acceptance Criteria for Emergency Core Cooling Systems for Light-Water Nuclear Power Reactors" (NRR &RES)

Primary Performance Goal: *Maintain safety, protection of the environment, and of the common defense and security*

Strategy 8: *We will continue to develop and incrementally use risk-informed and, where appropriate, less-prescriptive performance-based regulatory approaches to maintain safety.*

Secondary Performance Goal: *Reduce unnecessary regulatory burden on stakeholders*

Strategy 1: *We will utilize risk information and performance-based approaches to reduce unnecessary regulatory burden.*

In SECY-98-300, "Options for Risk-Informed Revisions to 10 CFR Part 50 - Domestic Licensing of Production and Utilization Facilities," dated December 23, 1998, the staff proposed three options for modifying regulations in 10 CFR Part 50 to better reflect the results of PRAs and the current understanding of reactor safety issues. The purpose of one of these options (Option 3) was to identify possible changes to specific technical requirements in Part 50, to evaluate the feasibility of such changes and to implement the changes. The Commission approved the staff's proposal and the staff provided its more detailed plan for the identification and evaluation phases of the Option 3 work in SECY-99-264, "Proposed Staff Plan for Risk-Informing Technical Requirements in 10 CFR Part 50," dated November 8, 1999. The Commission approved proceeding with the plan in a February 3, 2000 SRM.

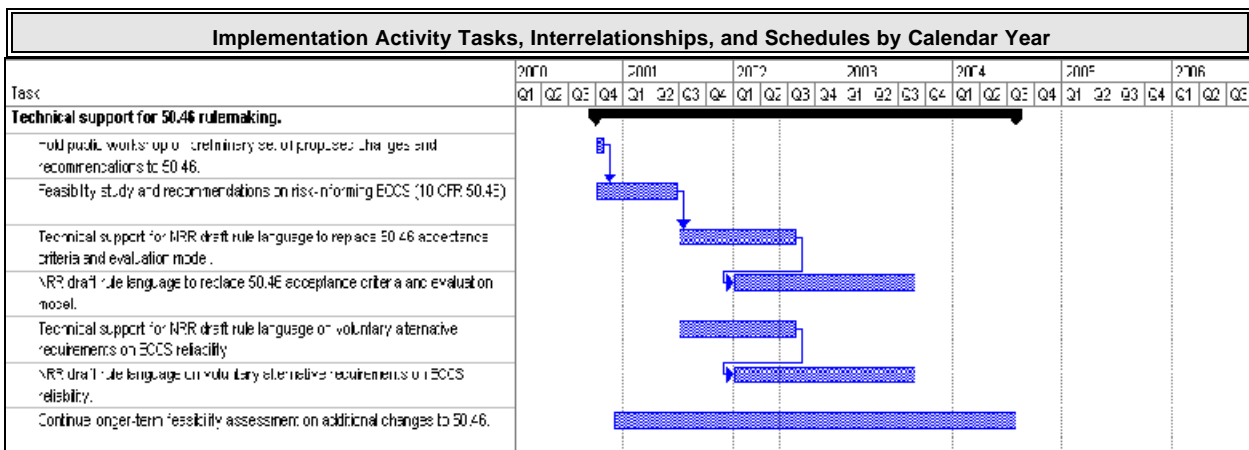
The staff concluded that it is feasible to change the technical requirements of 10 CFR 50.46 and recommended to the Commission in SECY-01-0133 and SECY-02-0057 (update to SECY-01-0133) that the requirements be changed via the rulemaking process. The staff has recommended that separate rulemakings be pursued for proposed changes to: 1) reliability requirements, 2) ECCS acceptance criteria, and 3) ECCS evaluation model requirements. The staff is now performing technical studies to help define the technical content of the rule changes. An initial draft report on the approach for modifying the ECCS reliability requirements was provided to NRR/DRIP on May 2, 2002. The final version of this report, as well as reports on the technical bases to support rulemaking for the proposed changes to the ECCS acceptance criteria and evaluation model requirements, will be provided to NRR/DRIP in July 2002.

In the next two years, the staff will continue technical work to redefine the maximum break pipe sizes for use as the design basis accident. This will allow ECCS capability changes within the framework of RI-ISI requirements. Results will be based on probabilistic fracture mechanics (PFM) analyses of critical piping systems and benchmarked against expert elicitation and relevant service history. Technical work required for this effort includes: evaluation/revision of PFM codes, incorporation of the latest understanding of material degradation mechanisms and piping environments, simulation of service loading and piping residual stresses, and incorporation of realistic transient histories and initiating frequencies. The piping failure rates will be combined with LB LOCA initiating events from external and other events to determine the final LB LOCA frequencies.

RES Priority: 8.4

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2001	0.6 (NRR) <0.1 (RES)	201 (RES)
2002	4.0 (NRR) 1.8 (RES)	750 (RES)

Selected Major Milestones and Schedules			
Major Milestones	Original RIRIP Target Date	Revised Date	Completion Date
Develop technical basis for rule change: acceptance criteria and evaluation model requirements	July 2002		
Develop draft rule language to replace current ECCS acceptance criteria and to revise requirements for evaluation model	12 months after SRM		
Develop technical basis for rule change: voluntary alternative requirements generic option only	April 2002	July 2002	April 2002
Develop draft rule language on voluntary alternative requirements to ensure ECCS reliability commensurate with the frequency of challenge	12 months after SRM		
Conduct feasibility assessment of additional changes to 50.46, including rigorous analysis of LOCA frequencies	July 2004		



Implementation Activity: Evaluate the feasibility of additional changes to the technical requirements of 10 CFR Part 50 (RES)

Primary Performance Goal: *Reduce unnecessary regulatory burden on stakeholders*

Strategy 1: *We will utilize risk information and performance-based approaches to reduce unnecessary regulatory burden.*

In SECY-98-300, "Options for Risk-Informed Revisions to 10 CFR Part 50 - Domestic Licensing of Production and Utilization Facilities," dated December 23, 1998, the staff proposed three options for modifying regulations in 10 CFR Part 50 to better reflect the results of PRAs and the current understanding of reactor safety issues. The purpose of one of these options (Option 3) was to identify possible changes to specific technical requirements in Part 50, to evaluate the feasibility of such changes, and, upon approval of the Commission, to change those requirements via the NRC's rulemaking process. The Commission approved the staff's proposal in a June 8, 1999, Staff Requirements Memorandum (SRM). The staff provided its more detailed plan and schedule for the identification and evaluation phases of the Option 3 work in SECY-99-264, "Proposed Staff Plan for Risk-Informing Technical Requirements in 10 CFR Part 50," dated November 8, 1999. The Commission approved proceeding with the plan in a February 3, 2000 SRM.

As discussed previously, the staff has concluded that it is feasible to change the technical requirements of 10 CFR 50.44 and 50.46. The staff will continue to solicit additional input on potential changes to the Part 50 technical requirements in public meetings and workshops. Subject to availability of resources, the staff will evaluate the feasibility of additional changes to the technical requirements.

RES Priority: 6.6

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2001	0.8	200
2002	0.2	0

Selected Major Milestones and Schedules			
Major Milestones	Original Target Date	Revised Date	Completion Date
Provide recommendations and feasibility report to Commission on other Part 50 changes	June 2001		July 2001
Conduct public workshop to solicit suggestions	December 2001	TBD	
Provide recommendations and feasibility of changes to other rules	TBD		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year																	
Task	2002															2003	
	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	
Assess/prioritize additional risk-informed and performance-based changes to Part 50.																	
Develop description of staff-suggested additional changes.																	
Issue FR notice on workshop, providing description of staff-suggested changes and soliciting stakeholder input.																	
Hold public workshop -- Date to be determined.																	

Implementation Activity: Develop risk-informed improvements to the standard technical specifications (STS). (NRR)

Primary Performance Goal: *Maintain safety, protection of the environment, and of the common defense and security.*

Strategy 8: *We will continue to develop and incrementally use risk-informed and, where appropriate, less prescriptive performance-based regulatory approaches to maintain safety.*

Secondary Performance Goal: *Make NRC activities and decisions more effective, efficient, and realistic.*

Strategy 1: *We will use risk information to improve the effectiveness and efficiency of our activities and decisions.*

Secondary Performance Goal: *Reduce unnecessary regulatory burden on stakeholders*

Strategy 1: *We will utilize risk information and performance-based approaches to reduce unnecessary regulatory burden.*

Consistent with the Commission's policy statements on technical specifications and the use of PRA, the NRC and the industry continue to develop risk-informed improvements to the current system of technical specifications. These improvements are intended to maintain or improve safety while reducing unnecessary burden and to bring technical specification requirements into congruence with the Commission's other risk-informed regulatory activities.

Proposals for risk-informed improvements to the STS are judged based on their ability to maintain or improve safety, the amount of unnecessary burden reduction they will likely produce, their ability to make NRC's regulation of plant operations more efficient and effective, the amount of industry interest in the proposal, and the complexity of the proposed change. The staff is re-evaluating the priorities for its review of risk-informed technical specification initiatives. The staff intends to follow the process described in NRC Regulatory Issue Summary 2000-06, "Consolidated Line Item Improvement Process For Adopting Standard Technical Specifications Changes for Power Reactors," for reviewing and implementing these improvements to the STS.

The industry and the staff have identified eight initiatives to date for risk-informed improvements to the STS. They are: 1) define the preferred end state for technical specification actions (usually hot shutdown for PWRs); 2) increase the time allowed to delay entering required actions when a surveillance is missed; 3) modify existing mode restraint logic to allow greater flexibility (i.e., use risk assessments for entry into higher mode limiting conditions for operation (LCOs) based on low risk); 4) replace the current system of fixed completion times with reliance on a configuration risk management program (CRMP); 5) optimize surveillance frequencies; 6) modify LCO 3.0.3 actions to allow for a risk-informed evaluation to determine whether it is better to shut down or to continue to operate; 7) define actions to be taken when equipment is not operable but is still functional; and 8) risk-inform the scope of the TS rule.

NRR Priority: 9.0

Project Considerations: The staff has completed initiative 2 and is nearing completion of its review of initiative 3. A status for the review of the rest of the initiatives is provided:

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2001	1.0	0
2002	4.0	0

Selected Major Milestones and Schedules			
Major Milestones	Original Target Date	Revised Date	Completion Date
Initiative 1 - Write safety evaluation for CE PWRs, BWRs	June 2002		
Initiative 2 - Completed			
Initiative 3 - Write safety evaluation for all plants	June 2002		
Initiatives 4, 5, 6, 7, &8	TBD		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year																		
Task	2000		2001				2002				2003				2004		2005	
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2
Plan and implement risk-informed standard technical specifications (STS).																		

Implementation Activity: Fire protection for nuclear power plants. (NRR)

Primary Performance Goal: *Maintain Safety, protection of the environment, and of the common defense and security*

Strategy 8: *We will continue to develop and incrementally use risk-informed and, where appropriate, less prescriptive performance-based regulatory approaches to maintain safety.*

Subactivity 1: Voluntary alternative to NRC existing fire protection regulations

The staff worked with the National Fire Protection Association (NFPA) to develop an alternative performance-based risk-informed fire protection standard for nuclear power plants. This standard, NFPA-805, was issued in April 2001. The staff has published draft rule language on the NRC ruleforum and is preparing proposed rule language for publishing in the *Federal Register*. The staff is working with the industry to develop implementing guidance for NFPA 805 that will be endorsed by the NRC in a regulatory guide.

Subactivity 2: Circuit Analysis Resolution Program

Another activity related to fire protection is the Circuit Analysis Resolution Program. In response to the need to resolve post-fire safe shutdown, fire-induced circuit failure analysis issues, the Boiling Water Reactor Owners Group (BWROG) and the Nuclear Energy Institute (NEI) have respectively developed deterministic and risk-informed post-fire safe shutdown methodology documents. These two documents have recently been combined into one document which provides a step-by-step means of deterministically conducting safe shutdown analyses, while it is intended to provide optional risk-informed methods for selected analytical steps. NEI has performed fire tests in an attempt to validate its methodology.

NEI has also assembled and completed work of an Expert Panel to evaluate the test results. NEI submitted NEI 00-01, "Guidance for Post-Fire Safe Shutdown Analysis," Draft Revision C, to the staff in October 2001. The staff reviewed the document and submitted their comments to NEI in March 2002. An ACRS Fire Protection Subcommittee is scheduled to discuss this topic in June 2002.

NRR Priority: 6.0

Project Considerations: Improvements to PRA fire methods are critical to these efforts.

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2001	0.3 (Subactivity 1) 2.0 (Subactivity 2)	0 100
2002	0.4 (Subactivity 1) 2.0 (Subactivity 2)	0 400

Selected Major Milestones and Schedules			
Major Milestones	Original Target Date	Revised Date	Completion Date
Publish proposed rule	October 2001	July 2002	
Issue final rule	April 2002	February 2004	

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year																
Task	2001				2002				2003				2004			
	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2
Develop a voluntary alternative to fire protection regulation 10 CFR 50.46.																

Implementation Activity: **Develop alternative requirements for safeguards that are risk-informed and/or performance-based. (NSIR)**

Primary Performance Goal: *Maintain safety, protection of the environment, and of the common defense and security*

Strategy 8: *We will continue to develop and incrementally use risk-informed and, where appropriate, less prescriptive performance-based regulatory approaches to maintain safety.*

Prior to the events of 9/11, the staff had underway a comprehensive review of 10 CFR 73.55. The staff intended to include a requirement for power reactor licensees to conduct drills and exercises to evaluate their protective strategy against a simulated design basis threat. The proposed rule required that licensees' security programs be based on risk-informed target sets of equipment necessary to prevent core damage and/or spent fuel sabotage.

On June 4, 2001, the staff forwarded to the Commission its proposed rule, recommending publication for public comment (SECY-01-0101: "Proposed Rule Changes to 10 CFR 73.55: Requirements for Physical Protection of Licensed Activities at Nuclear Power Reactors Against Radiological Sabotage"). However, to properly consider the events of September 11, 2001 and their impacts on physical security, the staff later recommended the withdrawal of SECY-01-0101. The Commission accepted this recommendation on October 30, 2001. Efforts in this area are on hold pending completion of the staff's ongoing top-to-bottom review of safeguards and security.

NSIR Priority: TBD

Project Considerations: Prior to the events of 9/11, the proposed rule permitted the application of risk-informed identification of target sets of equipment vital to preventing core damage and/or spent fuel sabotage. It also made the physical security requirements more performance-based, providing greater flexibility to licensees in designing their physical security program by reducing deterministic requirements and providing performance criteria. The rulemaking is currently on hold, as discussed previously.

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2001	3.7	120
2002	TBD	0

Selected Major Milestones and Schedules			
Major Milestones	Original Target Date	Revised Date	Completion Date
Proposed rule to Commission	May 2001		June 2001
Final rule to Commission	June 2003	TBD	
Proposed rule withdrawn due to 9/11 events			October 2001

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year																
Task	2000		2001				2002				2003				2004	
	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Revise 10 CFR 73.55																
Develop proposed rule																
Develop final rule																
NOTE: Schedule was developed prior to 9/11. Revised schedule to be determined when rulemaking activities are resumed.																

Implementation Activity: Develop the technical basis to revise the PTS rule. (RES)

Primary Performance Goal: *Maintain safety, protection of the environment, and the common defense and security*

Strategy 8: *We will continue to develop and incrementally use risk-informed and, where appropriate, less prescriptive performance-based regulatory approaches to maintain safety.*

In 1986, the NRC established the Pressurized Thermal Shock Rule (10 CFR 50.61) in response to an issue concerning the integrity of embrittled reactor pressure vessels in pressurized water reactors. The NRC staff is now reevaluating the technical basis of this rule in light of the results of subsequent extensive research on key technical issues underlying the rule. Analyses performed as part of this research suggest that the agency may be able to reduce unnecessary conservatism in the rule, while still maintaining safety.

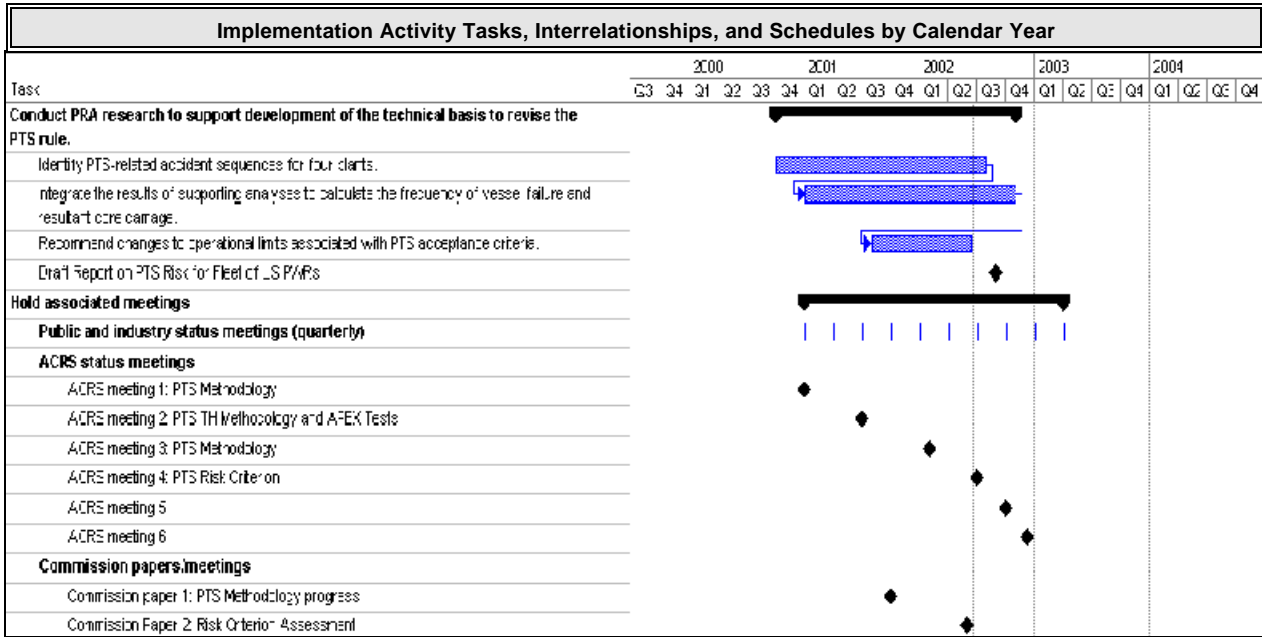
The staff's approach for reevaluating the screening criteria that 10 CFR 50.61 prescribes for reactor pressure vessel material characteristics is described in SECY-00-0140, "Reevaluation of the Pressurized Thermal Shock Rule (10 CFR 50.61) Screening Criterion," dated June 23, 2000, and subsequent periodic status reports identified as SECY-01-0045, SECY-01-0185, and SECY-02-0092, dated March 16, 2001, October 5, 2001, and May 30, 2002, respectively.

RES Priority: 8.4

Project Considerations: The timely completion of activities associated with this implementation activity requires close coordination, cooperation, and communication among numerous organizational units.

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2001	4.0	1000
2002	4.2	1253

Selected Major Milestones and Schedules			
Major Milestones	Original Target Date	Revised Date	Completion Date
Identify accident sequences significant to PTS for three representative plants	October 2001	August 2002	
Integrate the results of thermal/hydraulic, fracture mechanics, and sequence frequency analyses, using a probabilistic fracture mechanics code (FAVOR), to calculate the frequency of vessel failure and the resultant core damage.	January 2002	October 2002	
Recommend changes associated with PTS screening criteria	January 2002	November 2002	



Implementation Activity: PRA Review of Advanced Reactor Applications (NRR & RES)

Primary Performance Goal: *Maintain safety, protection of the environment, and the common defense and security*

Strategy 8: *We will continue to develop and incrementally use risk-informed and, where appropriate, less prescriptive performance-based regulatory approaches to maintain safety.*

The staff is developing a PRA plan for the development of methods, data, and tools needed for reactor-specific PRAs to support the evaluation of the design and operational characteristics of advanced reactors that are different from those of current reactors. The PRA plan will consider such things as the quantification of initiating events, likely accident phenomena, accident progression, containment-confinement performance, passive systems, digital instrumentation and control systems, uncertainties, internal flooding, external events (fires and seismic events), and multiple reactor modules on a site. The PRA is expected to interact with work in other areas related to advanced reactors, such as thermal/hydraulics (success criteria), severe accident progression (accident sequence identification), and the development of decision making criteria (risk-important insights).

NRR Priority: Not yet prioritized

RES Priority: 5.0

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2001	0	0
2002	TBD	TBD

Selected Major Milestones and Schedules			
Major Milestones	Original Target Date	Revised Date	Completion Date
TBD			

Implementation Activity: Develop methods for assessing steam generator performance during severe accidents. (RES)

Primary Performance Goal: *Maintain safety, protection of the environment, and the common defense and security*

Strategy 8: *We will continue to develop and incrementally use risk-informed and, where appropriate, less prescriptive performance-based regulatory approaches to maintain safety.*

The integrity of steam generator tubes in pressurized water reactors is a key consideration in maintaining plant safety during design basis and severe accidents. Design basis accident tube ruptures can result in offsite radioactive releases that could require emergency response and approach the limits of the 10 CFR 100 siting requirements. Severe accident tube ruptures, in which a tube rupture either initiates the accident or occurs during the accident, can result in bypass of the containment structure and subsequent large offsite health consequences. As such, methods to assess the integrity of tubes during normal operations and to repair deficient tubes are an important element of the industry's safety programs and the staff's regulatory activities.

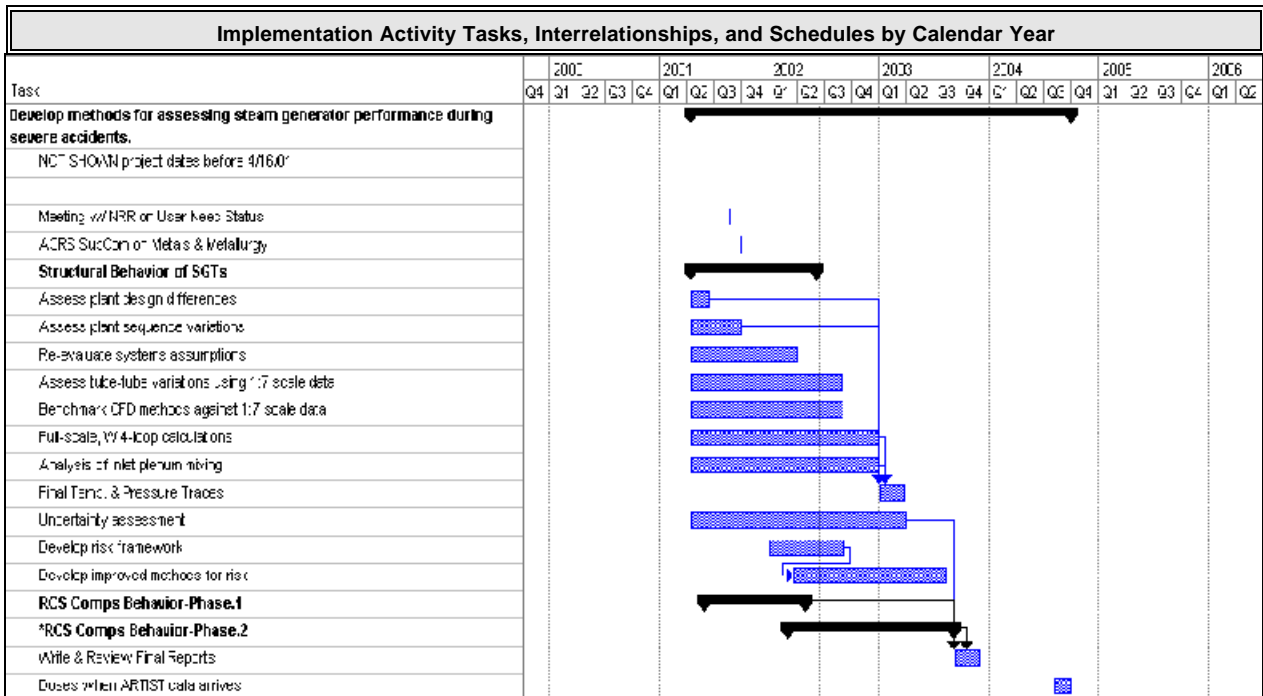
The staff is working to develop methods and tools to address steam generator tube integrity during postulated severe accidents in pressurized water reactors. The plan for the work includes four parts: probabilistic risk analysis, thermal hydraulics, structural behavior of steam generator tubes and other reactor coolant system components, and offsite consequences. The thermal hydraulic part of this work was initiated in FY 2001, with remaining aspects to be initiated in FY 2002.

RES Priority: 7.6

Project Considerations: The timely completion of activities associated with this implementation activity requires close coordination, cooperation, and communication among numerous organizational units.

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2001		
2002	1.0	1,275

Selected Major Milestones and Schedules			
Major Milestones	Original Target Date	Revised Date	Completion Date
Meeting with NRR on user need status	August 2001		August 21, 2001
ACRS Subcommittee on Metals and Metallurgy	September 2001		September 27, 2001
RCS components -- Phase I	February 2002	April 2002	April 26, 2002
Structural behavior of SGTs	December 2001	June 2002	
Develop risk framework	March 2002	June 2002	
Full-scale W 4-loop calculations	March 2002	December	
Develop improved methods for risk	August 2003		
RCS components -- Phase II	September 2003		
Final Reports	December 2003		



Implementation Activity: Creating a risk-informed environment (NRR)

Primary Performance Goal: *Make NRC activities and decisions more effective, efficient, and realistic*

Strategy 1: *We will use risk information to improve the effectiveness and efficiency of our activities and decisions.*

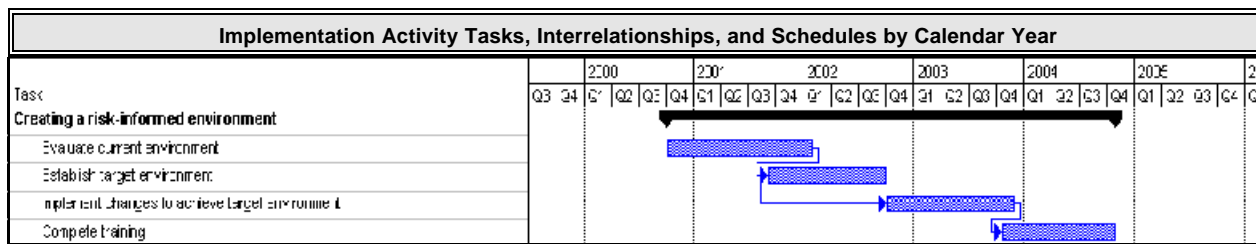
To help focus staff activities and resources in the reactor safety arena on those items most important to public health and safety, NRR has initiated a three year program whose objective is to create an environment in which risk-informed methods are integrated into staff activities and staff plans and actions are naturally based on the principles of risk-informed regulation. The staff's plan for this program includes the following activities:

- ▶ Survey and assess staff, management and Commission perspectives on using risk-informed approaches through focus group meetings and interviews;
- ▶ Analyze past efforts to risk-inform processes in the reactor safety arena to determine lessons learned and best practices;
- ▶ Determine and implement ways in which best practices for using risk-informed approaches for assessing the significance or priority of issues before the staff can be identified and shared among personnel in the reactor safety arena;
- ▶ Evaluate effectiveness of instruments that (1) facilitate the sharing of risk knowledge and information and best practices for making assessments of risk significance among personnel in the reactor program and (2) deliver training on the use of risk-informed approaches and methods; make improvements as necessary
- ▶ Prepare Office Instructions and other guidance documents as necessary;
- ▶ Communicate the philosophy, policy and practices of risk-informed regulation to staff;
- ▶ Assess program effectiveness using surveys and focus group meetings.

NRR Priority: 10.0

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2001	2.0	200
2002	4.0	200

Selected Major Milestones and Schedules			
Major Milestones	Original Target Date	Revised Date	Completion Date
Evaluate current environment for implementing risk-informed regulation in the reactor program, including current policies, practices, information base, methods and channels of communication, and staff and management perspectives.	December 2001	February 2002	February 2002
Design a target environment for risk-informed regulation acceptable to all stakeholders in the reactor program.	May 2002	October 2002	
Implement changes to achieve target environment	October 2003		
Assess Effectiveness of Changes	October 2004		



Implementation Activity: **Develop standards for the application of risk-informed, performance-based regulation in conjunction with national standards committees (RES & NRR)**

Primary Performance Goal: *Make NRC activities and decisions more effective, efficient, and realistic.*

Strategy 1: *We will use risk information to improve the effectiveness and efficiency of our activities and decisions.*

The increased use of probabilistic risk assessments (PRA) in the regulatory decision-making process requires consistency in the quality, scope, methodology and data used in such analyses. These requirements apply to PRAs developed by industry to support specific, risk-informed licensing actions as well as to PRAs developed by NRC staff to analyze specific technical issues or to support Commission decisions. To this end, NRC worked with the American Society of Mechanical Engineers (ASME) to develop a national consensus standard setting forth specific guidance regarding the construction and execution of a PRA covering internal initiating events (excluding internal fire) at full power operation for a level 1 and limited level 2 (large early release frequency only) PRA. This standard, which was issued in April 2002, will help to ensure that PRAs developed in accordance with the standard are robust, consistent, and defensible and are documents from which regulatory decisions can confidently be made. In parallel, the staff also worked with the National Fire Protection Association (NFPA) to develop standards for fire risk analysis (See activity RS-MS8-6).

The NRC staff has been working with the American Nuclear Society (ANS) to develop a companion standard covering probabilistic analyses that would include the risk of internal fire, the impacts of external events on plant risk, and risk-significant events that could occur when a plant is operating at low power or when shutdown (LP/SD).

The NRC staff is cooperating with ASME and other organizations to incorporate risk insights into codes and standards applicable to various activities at nuclear power plants. For example, ASME is updating the *Code for Operation and Maintenance of Nuclear Power Plants* and applicable Code Cases to allow the use of risk insights in the inservice testing of pump and valves. ASME is also developing Code Cases under Section XI of the *Boiler & Pressure Vessel Code* to apply risk insights in the inservice inspection of structures, systems, and components. In addition, the Nuclear Energy Institute is developing guidelines for the implementation of risk-informed alternatives to the requirements in Part 50 of Title 10 to the *Code of Federal Regulations*.

RES Priority: 9.6

NRR Priority: 6.0

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2001	<0.1 (NRR) 0.1 (RES)	335 (RES)
2002	<0.1 (NRR) 0.1 (RES)	300 (RES)

Selected Major Milestones and Schedules			
Major Milestones ¹	Original Target Date	Revised Date	Completion Date
Final PRA standard issued by ASME	March 2001	March 2002	April 2002
Final PRA standards issued by ANS on External Hazards	June 2001	December 2002	
Final PRA standards issued by ANS on Low Power/Shutdown	June 2001	December 2003	
Final standard issued by ANS on Internal Fire	Schedule TBD		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year														
Task	2002				2003				2004				2005	
	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Support development of standards for probabilistic risk assessment by national standards committees, in support of NRC work to extend the use of PRA in agency regulatory activities.														
Review and public comment on final draft ANS external hazards standard.														
Develop revisions to ANS external hazards standard to reflect comments.														
Final external hazards standard issued by ANS.														
Final ASME standard on internal events issued.														
Draft PRA standard on LPSD issued by ANS for ACRS and public comment.														
Final PRA standard published by ANS on LPED														

¹Recognizing that control of these projects properly rests with the standards committees, these milestones have been established by these organizations.

Implementation Activity: Develop improved methods for calculating risk in support of risk-informed regulatory decision making (RES)

Primary Performance Goal: *Make NRC activities and decisions more effective, efficient, and realistic.*

Strategy 1: *We will use risk information to improve the effectiveness and efficiency of our activities and decisions.*

Decisions to pursue development of methods and models are made based on three general considerations: (1) the importance of new methods to risk informing our regulations; (2) the adequacy of existing methods for understanding the risk implications of experimental findings and operational experience; and (3) the availability of methods for assessing the risk associated with the introduction of new technologies and new reactor designs. These criteria are associated with the issue of PRA model completeness and the degree to which PRA models adequately characterize risk-important failure modes and mechanisms. Thus, the more complete our understanding of plant risk, the more free are we to identify and remove unnecessary conservatism from our regulations and decision-making.

With these three considerations in mind, the following research efforts have been identified:

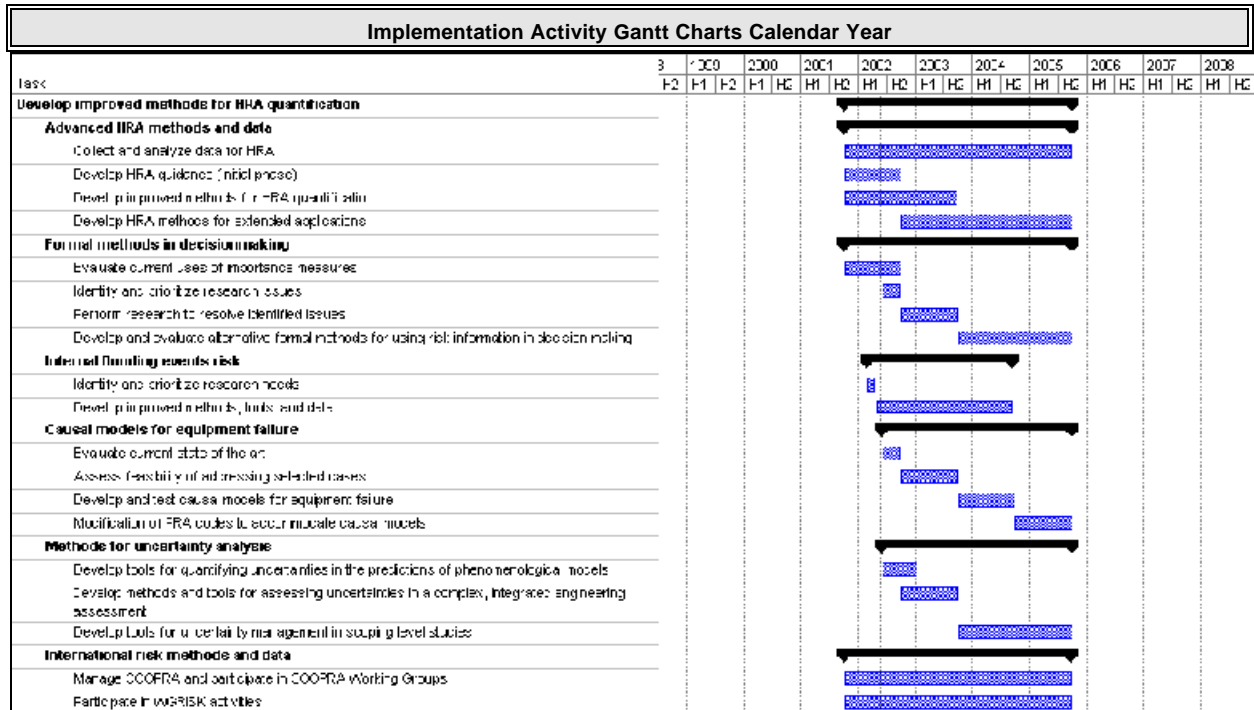
- Advanced human reliability analysis (HRA) data and methods
- Methods for Level 2 PRA
- Formal methods in decision making
- Internal flooding events risk
- Causal models for equipment failure
- Methods for uncertainty analysis
- International risk methods and data

RES Priority: 8.2

Project Considerations: The quality of risk assessments is highly dependent upon the quality of the engineering analysis (e.g., thermal-hydraulic, severe accident, structural) that is used to calculate plant performance and success criteria. Although not included in this plan, work to improve and ensure the analytical tools used for these analyses are realistic and readily useable is vital to the success of risk-informed regulation.

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2001	3	1074
2002	2	800

Selected Major Milestones and Schedules			
Major Milestones	Original Target Date	Revised Date	Completion Date
Complete review and initial evaluation of potential HRA data sources	June 2002		
Summarize insights from HRA R&D for HRA reviewers	September 2002		
Summarize issues associated with current uses of importance measures	September 2002		
Develop approach for addressing uncertainties in fire risk assessment	December 2002		
Complete feasibility study on developing PRA models on QA effects	September 2001	September 2002	
Convene sixth international cooperative PRA research program meeting	December 2003		



Implementation Activity: Develop and apply methods for assessing fire safety in nuclear facilities (RES)

Primary Performance Goal: *Make NRC activities and decisions more effective, efficient, and realistic.*

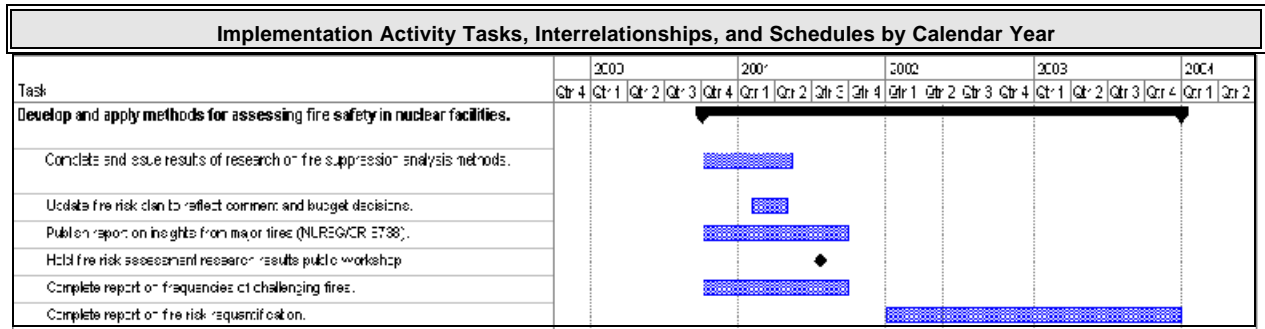
Strategy 1: *We will use risk information to improve the effectiveness and efficiency of our activities and decisions.*

The development of performance-based fire standards and regulations requires a sound understanding of fire and its contribution to power plant risk. Current fire PRA models are not adequate to support credible, risk-informed changes to these standards and regulations. A fire risk program has been developed and is being implemented to address the complex issues associated with fire risk.

RES Priority: 8.2

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2001	1.0	469
2002	2.3	750

Selected Major Milestones and Schedules			
Major Milestones	Original RIRIP Target Date	Revised Date	Completion Date
Revised plan for fire risk	November 2000		May 2001
Issue report on fire suppression analysis methods	December 2000		April 2001



Implementation Activity: Develop and maintain analytical tools for staff risk applications (RES)

Primary Performance Goal: *Make NRC activities and decisions more effective, efficient, and realistic.*

Strategy 1: *We will use risk information to improve the effectiveness and efficiency of our activities and decisions.*

The NRC has developed and maintains the SAPHIRE (Systems Analysis Programs for Hands-on Analysis Integrated Reliability Evaluations) computer code for performing probabilistic risk analysis (PRAs). SAPHIRE offers state-of-the-art capability for assessing the risk associated with core damage frequency (Level 1 PRA) as well as the risk from containment performance and radioactive releases (Level 2 PRA). SAPHIRE supports the Agency's risk informed activities, which include analyses risk-informing part 50, vulnerability assessment, advanced reactors, operational experience, generic issues, and regulatory backfit. The continual advancement of the state-of-the-art in the use of computers and continual expansion of the use of risk information in the NRC's decision-making process necessitates a continuous support of SAPHIRE. Therefore, the staff plans to continue maintaining and improving the SAPHIRE code.

RES Priority: 7.2

Project Considerations: These analytical tools provide support to SPAR and generic issue assessment.

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2001	0.1	279
2002	0.1	300

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year													
Task	2000				2001				2002				2003
	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1
Maintain analytical tools for staff risk applications.													
Continue SAFHIRE computer code data entry and maintenance													

Implementation Activity: Assess regulatory effectiveness using risk information. (RES)

Primary Performance Goal: *Make NRC activities and decisions more effective, efficient, and realistic*

Strategy 1: *We will use risk information to improve the effectiveness and efficiency of our activities and decisions.*

The staff will conduct an integrated evaluation of risk information, inspection findings, operating experience, domestic and international research results, and cost data to identify ways to improve the effectiveness of NRC regulatory requirements, guidance, and processes.

RES Priority: 9.6

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2001	3.8	267
2002	2.3	450

Selected Major Milestones and Schedules			
Major Milestones	Original Target Date	Revised Date	Completion Date
Evaluate effectiveness of ATWS rule	April 2001		April 2001
Evaluate effectiveness of USI A-45 resolution	September 2001	February 2003	
Evaluate effectiveness of 10CFR50, App J, Option B	January 2002	September 2002	

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year												
Task	2001			2002			2003					
	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	
Assess regulatory effectiveness using risk information.												
Propose a risk-informed, performance-based approach to regulatory oversight.												
Complete plant-specific risk-insight packages for all NPPs for IRO.												
Finalize assessment of effectiveness of ATWS rule.												
Evaluate effectiveness of 10 CFR 50 Appendix J, Option B												
Evaluate effectiveness of USI A-45 resolution for internal peer review.												

Implementation Activity: **Develop a regulatory guide and accompanying SRP chapter providing an approach for assessing the adequacy of PRA results used in support of regulatory applications.**

Primary Performance Goal: *Make NRC activities and decisions more effective, efficient, and realistic.*

Strategy 1: *We will use risk information to improve the effectiveness and efficiency of our activities and decisions.*

The NRC is extensively using information from probabilistic risk assessments (PRAs) in its regulatory decision-making. To streamline staff review of licensee applications using risk insights, professional societies and the industry undertook the following initiatives for establishing consensus standards and guidance on the use of PRA in regulatory decision-making:

- ! The American Society of Mechanical Engineers (ASME) has developed a standard for a Level 1 analyses (i.e., estimation of core damage frequency (CDF)) and a simplified Level 2 analysis (i.e., estimation of large early release (LERF)) covering internal events (transients, loss of coolant accidents, and internal flood) at full power.
- ! The Nuclear Energy Institute (NEI) has developed a "PSA Peer Review Guidance," (NEI-00-02) covering internal events at full power--Level 1 and simplified Level 2.
- ! The American Nuclear Society (ANS) is developing PRA standards for:
 - external hazards with a tentative publication date of December 2002
 - low power and shutdown with a tentative publication date of December 2003
 - internal fires (with no date available at this time because ANS is in initial stages)

It is expected that licensees will use the PRA standards and industry guidance to help demonstrate and document the adequacy of their PRAs for a variety of risk-informed regulatory applications. Therefore, the staff should document its position on the adequacy of the standards and industry guidance to support regulatory applications. Such documentation will indicate in which areas staff review can be minimized and where additional review may be expected. To accomplish this, the staff will publish a new regulatory guide (RG) providing an approach for assessing the adequacy of PRA results used in support of regulatory applications and an accompanying Standard Review Plan (SRP) chapter.

The Regulatory Guide and associated SRP chapter are intended to support all risk informed activities. The main body of the RG will: (1) summarize Attachment 1 of SECY-00-0162 and (2) provide advice on the use of PRA standards and industry guidance by licensees to determine the level of confidence that can be afforded PRA insights/results. The staff's position on each PRA standard and industry guidance will be provided in the appendices.

RES Priority: TBD

NRR Priority: 6.0

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2002	0.4 (NRR) 0.5 (RES)	250 (RES)

Selected Major Milestones and Schedules			
Major Milestones ²	Original Target Date	Revised Date	Completion Date
Main Body of Reg Guide	December 2002		
Appendix A: Staff position on the PRA standard issued by ASME on internal events	December 2002		
Appendix B: Staff position on the PRA review guidance issued by NEI on internal events (NEI-00-02)	December 2002		
Appendix C: Staff position on PRA standards issued by ANS on External Hazards	December 2003		
Appendix D: Staff position on standards issued by ANS on Low Power/Shutdown	December 2004		
Appendix E: Staff position on PRA standards issued by ANS on internal fire	TBD		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year																
Task Name	2002				2003				2004				2005			
	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1		
Develop Reg Guide and SRP to provide an approach for characterizing quality of PRA results	[Gantt bar spanning from Qtr 4 2002 to Qtr 4 2004]															
Develop Reg Guide	[Gantt bar spanning from Qtr 4 2002 to Qtr 4 2004]															
Develop RG Appendix A: staff position on ASME standard	[Gantt bar spanning from Qtr 4 2002 to Qtr 4 2004]															
Develop RG Appendix B: staff position on industry guidance	[Gantt bar spanning from Qtr 4 2002 to Qtr 4 2004]															
Develop RG Appendix C: staff position on ANS external hazards standards	[Gantt bar spanning from Qtr 1 2003 to Qtr 4 2003]															
Develop RG Appendix D: staff position on ANS low power/shutdown standards	[Gantt bar spanning from Qtr 1 2004 to Qtr 4 2004]															
Develop RG Appendix E: staff position on ANS internal fire standards	[Gantt bar spanning from Qtr 1 2004 to Qtr 4 2004]															

²Recognizing that control of these projects rests with the standards committees, milestones have been established by and are under the control of these organizations.

Chapter 2. Nuclear Materials and Waste Safety Arenas

Carl J. Paperiello, Arena Manager

2.1. INTRODUCTION

As directed by the Commission, the Office of Nuclear Materials Safety and Safeguards (NMSS) has been actively moving towards increasing the use of risk insights and information in its regulatory applications, where appropriate. NMSS is responsible for regulatory applications in the nuclear materials safety and nuclear waste safety arenas. Regulatory applications include, but are not limited to, rulemaking, guidance development, licensing and certification, and inspection activities for fuel cycle facilities, industrial and medical licensees, site decommissioning, transportation, and waste management and disposal.

Because of the varied nature of the activities in these two arenas, a single approach to “risk-informing” the NMSS regulatory applications, such as the probabilistic risk analyses (PRA) approach adopted by the Office of Nuclear Reactor Regulation, is not feasible. In the past, NMSS has used risk information in making regulatory decisions on a case-by-case basis. More recently, however, NMSS has developed a relatively comprehensive plan to risk-inform its regulatory applications, in consultation with the Commission. Currently, NMSS is implementing the plan.

The following sections briefly discuss the history behind the development and implementation of the NMSS plan for risk-informing its activities, as well as the plan itself and the current status of implementation. The discussion of the plan is followed by a detailed description of current risk-informed initiatives and activities.

2.2 BACKGROUND

DSI-12 The Commission’s Strategic Assessment and Rebaselining initiative included a Direction-Setting Issue focused on risk-informed, performance-based regulation (DSI-12). In a Staff Requirements Memorandum for COMSECY-96-061 (April 15, 1997) that addressed DSI-12, the Commission provided the following direction regarding the use of risk information in the nuclear materials and waste safety arenas:

The staff should also reexamine the applicability of its risk-informed, performance-based or risk-informed less prescriptive approaches with regard to nuclear material licensees and to high level waste issues, to ensure that the needs of those licensees and those areas receive adequate consideration. The staff should perform a review of the basis for nuclear materials regulations and processes, and should identify and prioritize those areas that are either now, or could be made, amenable to risk-informed, performance-based or risk-informed less prescriptive approaches with minimal additional staff effort/resources. This assessment should eventually lead to the development of a framework for applying PRA to nuclear material uses, similar to the one developed for reactor regulation (SECY-95-280), where appropriate.

SECY-98-138 NMSS staff provided an initial response to the Commission in SECY-98-138 (June 11, 1998), informing the Commission that it reviewed the framework for applying PRA to reactor regulation and evaluated the applicability of the reactor framework to nuclear materials and waste applications. The staff determined that, while the reactor framework and a materials and waste framework would be similar in purpose and principles, a materials and waste framework would likely differ from the reactor framework in some of its specifics. The staff provided a detailed discussion of assumptions that would underlie, and elements that would be incorporated into, a materials and waste framework and provided a schedule for developing the framework.

In SECY-98-138, the staff also identified several gaps in the foundation of pertinent experience and policy necessary to develop and apply a framework to material and waste applications:

- limited experience with strengths and limitations of potentially useful analytical methods;
- limited knowledge of which of these methods may be applied usefully to a specific nuclear materials use;
- lack of established policy (similar to the reactor safety goal policy statement); and
- insufficient staff training programs.

The staff indicated that gaps in experience and knowledge would be addressed through ongoing risk-informed initiatives and activities that would test or develop system analysis methods for certain nuclear material and waste applications. The staff proposed to address policy gaps by recommending to the Commission (1) whether materials and waste safety goals should be developed, and (2) criteria for determining whether risk-informing a given materials or waste regulatory application is appropriate. Finally, the staff proposed to identify training necessary to implement the framework and to develop an appropriate training program.

SECY-99-100 NMSS staff completed its response to the Commission through SECY-99-100 (March 31, 1999), building on the information and proposals provided to the Commission in SECY-98-138. In SECY-99-100, the staff proposed a four-part framework for using risk assessment in nuclear materials waste regulation:

Part 1 - Define regulatory application areas in which risk assessment methods can play a role in NRC's decision-making process. Group the areas by regulated use (e.g., fuel fabrication) and within each use by regulatory application (e.g., graded quality assurance).

Part 2 - Evaluate the current considerations underlying the application area to ensure that the existing approach is altered only after careful consideration. Factors to be considered include: deterministic considerations (hazard, relative importance of human vs. equipment error, defense-in-depth, codes and standards); current risk considerations (e.g., use of performance assessment in geologic repository licensing); and institutional considerations (existing statutory requirements, Agreement State issues, and licensee circumstances).

Part 3 - Evaluate new risk considerations in support of the proposed regulatory action. Elements of this evaluation include: scope and level of detail of the risk assessment, sensitivity and uncertainty analyses, and assurance of technical quality.

Part 4 - Integrate the current considerations and new risk considerations to ensure a consistent and scrutable decision-making process and to ensure that the underlying bases for rules, regulations, regulatory guides, and staff review guidance are maintained or modified to the extent supported by the conclusions of Parts two and three.

The staff proposed a five-step process to implement the framework:

Step 1 - Identify candidate regulatory applications that are amenable to expanded use of risk assessment information (i.e., risk-informed approaches) and identify the responsible organizations.

Step 2 - Decide how to modify the current approach of the regulatory application areas that are determined to be amenable to risk-informed approaches.

Step 3 - Change regulatory approaches.

Step 4 - Staff training for implementing risk-informed approaches.

Step 5 - Develop or adapt risk-informed tools.

The staff proposed to accomplish the first step of the framework implementation process by identifying a full set of regulatory application areas and then screening them to establish a set of applications that would be amenable to risk-informed regulatory approaches. Because of limited resources, the staff proposed a step-by-step approach based on prioritization, rather than a comprehensive reevaluation in all areas simultaneously. Based on the screening, the staff would decide whether it seemed appropriate to change the existing regulatory framework and, if so, would propose risk metrics and goals as a basis for interaction with stakeholders. Such interaction would include stakeholder workshops, Internet postings, and possibly pilot projects.

To accomplish the second step of the framework implementation process, the staff proposed to use stakeholder workshops, Internet postings, and pilot projects as important sources of information to address the following considerations: (1) what specific use is the staff expected to make of risk insights and risk assessment in development of regulations and guidance, licensing, inspection, assessment, and enforcement; and (2) what specific use is the licensee expected to make of risk insights and risk assessment in planning and conducting its operations.

The third step of the framework implementation process proposed by the staff was to make the appropriate changes to the regulatory approaches, for example, by modifying rules and regulations, staff review plans, and regulatory guides. The fourth step of the proposed framework implementation process was staff training to assure consistent and knowledgeable implementation of the new risk-informed approaches, and the fifth step was to develop or adapt needed tools (e.g., risk assessment methods or computer codes).

In addition to the four-part framework for using risk assessment in nuclear materials and waste regulation, and the five-step process for implementing the framework, NMSS staff also proposed to develop risk metrics and goals to address risk management issues in regulating nuclear material uses and radioactive waste management and to support risk-informed policies and decision-making. Finally, SECY-99-100 proposed the formation of a joint Advisory Committee on Reactor

Safeguards (ACRS)/Advisory Committee on Nuclear Waste (ACNW) subcommittee to provide technical peer review of the staff's future efforts.

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SRM for SECY-99-100 On June 28, 1999, the Commission issued its Staff Requirements Memorandum (SRM) for SECY-99-100. The Commission approved (1) the staff's proposal to implement a framework for using risk assessment in regulating nuclear material uses and disposal; (2) the staff's proposal for addressing risk management issues, including the development of risk metrics and goals; and (3) the formation of a joint ACRS/ACNW subcommittee to provide technical peer review of the staff's efforts in this area. Also, the Commission approved the reprogramming of six staff full-time equivalents (FTEs) to proceed with this effort.

The Commission indicated that staff should develop appropriate material safety goals, analogous to the NRC reactor safety goal, to guide the NRC and to define what "safety" means for the materials program. The Commission directed the staff to develop these goals through an enhanced participatory process, including broad stakeholder participation. Also, in developing a standard or standards for risk-informed regulation in NMSS, the Commission indicated that the staff should give due consideration to existing radiation protection standards in Part 20, and that the standard(s) should allow for equivalent levels of reasonable assurance of adequate protection across the spectrum of regulated materials activities and should be consistent with risk-informed practices being applied to nuclear power plant regulation.

2.3 NMSS PLAN FOR RISK-INFORMING MATERIALS AND WASTE SAFETY ARENAS

NMSS is following a general, three-phase plan to implementing the framework described in SECY-99-100. The first two phases address the first step in the framework implementation process described in SECY-99-100 (identified above). The first phase focuses on developing a systematic approach for identifying candidate NMSS regulatory applications that may be amenable for increased use of risk information. The second phase focuses on applying the systematic approach, developed through the first phase, to identify the candidate NMSS regulatory applications. Finally, the third phase addresses steps two through five of the SECY-99-100 framework implementation process. The third phase focuses on the actual modification of the identified regulatory applications to make them more risk-informed. The three phases are shown in Figure 2-1. Each of these three phases is discussed below.

2.3.1 Phase 1

Phase 1 represents NMSS's initial implementation of the Commission three directives identified in the SRM for SECY-98-100 and described above in Section 2.2.

In August 1999, NMSS staff were identified and reassigned to form the NMSS Risk Task Group. The Risk Task Group currently reports to the Office of the Director, NMSS, reflecting the priority the Director places on increasing the use of risk information in the regulatory applications of NMSS. Also, the Director formed the NMSS Risk Steering Committee, comprised of management at the division and office level. The NMSS Risk Steering Committee provides management and policy direction to the Risk Task Group, as necessary.

Screening Criteria One of the first efforts of the Risk Task Group was the formulation of draft screening criteria for identifying NMSS regulatory applications amenable to increased use of risk

information. As part of the effort to use an enhanced public participatory process in developing the framework, the Risk Task Group held a public workshop in Washington, DC, on April 25 and 26, 2000. The Risk Task Group published draft screening criteria in a Federal Register Notice (65 FR 54323, March 16, 2000) announcing the workshop. The purpose of the workshop was to

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(1) solicit public comment on the draft screening criteria and their applications, and (2) solicit public input for the process of developing safety goals for nuclear materials and waste applications. The workshop included participation by representatives from NRC, Environmental Protection Agency, Department of Energy, Occupational Safety and Health Administration, Organization of Agreement States, Health Physics Society, Nuclear Energy Institute, environmental and citizen groups, licensees, and private consultants. A consensus among the workshop participants was that a case study approach and iterative investigations would be useful for the following purposes: (1) to test the screening criteria, (2) to show how the application of risk information has affected or could affect a particular area of the regulatory process, and (3) to develop safety goal parameters and a first draft of safety goals for each area. These are similar to the gaps in the NMSS foundation that should be addressed to support risk-informing regulatory applications, as identified by staff in SECY-98-138.

Based on feedback received from stakeholders, the Risk Task Group, in consultation with the Risk Steering Committee, finalized the draft set of screening criteria for identifying NMSS regulatory applications amenable to increased use of risk information. The draft criteria consisted of four criteria which addressed whether a benefit would be realized from modifying a regulatory approach, based on risk information. The four "benefit criteria" reflected the four performance goals identified in the NRC Strategic Plan: maintaining safety, protection of the environment, and the common defense and security; increasing public confidence; making NRC activities and decisions more effective, efficient, and realistic; and reducing unnecessary regulatory burden on stakeholders. The remaining three criteria addressed whether technical feasibility, implementation costs, or other factors would negate the potential benefits of, or significantly hinder, modifying the regulatory approach.

Case Studies Also based on the April 2000 public workshop, the Risk Task Group developed a plan for conducting a series of eight case studies (1) to test the usefulness and applicability of the draft screening criteria, (2) to evaluate how the application of risk information has affected or could affect particular areas of the NMSS regulatory process, and (3) to draft risk metrics and goals (i.e., safety goals) that may be used to address risk management issues in the NMSS materials and waste safety arenas. A draft of the case study plan was issued for public comment (65 FR 54323), a public workshop was held in September 2000, and the final case study plan was released in October 2000 (65 FR 66782).

The Risk Task Group began the case studies in November 2000. The case study areas were selected to reflect the diversity of NMSS materials and waste regulatory applications and include: regulation of generally licensed and specifically licensed devices (gas chromatographs, fixed gauges and static eliminators), decommissioning of the Trojan reactor site under the 10 CFR Part 20 license termination rule, transportation of the Trojan reactor vessel, regulation of uranium recovery facilities, certification of the Paducah gaseous diffusion plant, and licensing of the Idaho National Engineering and Environmental Laboratory independent spent fuel storage installation.

The case studies were completed and a final report was distributed in December 2001 to the NMSS Risk Steering Committee (*Risk-Informing the Materials and Waste Arenas: Integration of Case Studies and Related Risk Assessments*; December 2001; addenda February 2002; ADAMS ML013610470). The Risk Task Group met with the NMSS Risk Steering Committee in January 2002 and discussed the following conclusions:

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- A well-defined procedure for identifying candidate applications in NMSS for risk-informing was successfully tested and was finalized as a set of screening considerations. Overall, the case studies demonstrated that the screening considerations contained all the relevant elements needed for risk-informing and could be a useful decision-making tool. However, the application could be subjective, so guidance is needed. The experience of carrying out the case studies also indicated that the draft "screening criteria" should be more properly identified as screening considerations. They are a set of factors that encompass the relevant questions that are needed for risk-informing, but they do not have just yes/no answers.
- The case studies collectively illustrated that risk information has been used for some time in making regulatory decisions. The case studies were effective in indicating where decisions or processes are consistent with the Agency's strategic goals. Furthermore, they helped to highlight some of the areas in which there are shortcomings in the regulations or regulatory process.
- The studies also showed that safety goals are feasible and decision-making and risk management can be facilitated if a clear set of safety goals existed. A preliminary set of safety goals were developed and need to be tested and refined. Risks to the workers were found to be significant in comparison to public risks. For some facilities, chemical risks were found to be comparable to or greater than the radiological risks.
- Information, tools, methods, and guidance needs were identified and the necessary tools could be assembled to make the risk-informing process more effective in NMSS. There has been a fairly significant application of risk methods and applications in some areas and somewhat less experience in other areas. One of the major gaps in the methods is the identification and development of a robust and simple method for incorporating human factors and estimating human reliability in the very wide range of situations and activities encountered and performed by NMSS licensees.

Specific Risk-Informed Activities The primary Phase I activity described in the preceding paragraphs focused on the development of the general approach to systematically incorporate risk information into NMSS regulatory applications and support risk management decision-making. Concurrent with this activity, NMSS has been incorporating risk insights and information into specific regulatory applications. These applications were identified through several mechanisms, including operating experience, Commission direction, stakeholder suggestion, and staff initiatives. Where appropriate, NMSS staff responsible for these initial "risk-informed" applications interacted with Risk Task Group staff who are involved in the case studies and the development of the screening criteria and risk metrics and goals.

NMSS Risk Training Also during Phase I, NMSS began to develop a training program addressing the use of risk information in materials and waste regulatory applications. The need for this training program was identified in SECY-98-138. NMSS developed a three-tier program, reflecting the relative depth and complexity of the course content. Tier I and Tier II courses provide training on the general relevance of risk information and risk assessment methods in the materials and waste arenas to management, administrative and technical staff. Tier III courses provide training on specific aspects of risk assessment, management and communication. Tier III training needs are identified through interaction with the NMSS division-level management. NMSS developed and began to offer the Tier I and Tier II courses during 2000. NMSS began to develop and offer some of the initial Tier III courses during 2001.

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Phase I concluded in December 2001 with the completion of the case study activity, the finalization of the screening criteria for identifying regulatory applications, and the development of draft risk metrics and goals.

2.3.2 Phase 2

Phase 2 began in January 2002. The second phase of the NMSS plan to risk-inform its regulatory applications focused on applying a systematic approach to identify NMSS regulatory applications amenable to being risk-informed. This identification of activities will serve as the NMSS road map towards comprehensively risk-informing its regulatory activities. The second phase consisted of a systematic and comprehensive review of NMSS regulatory applications, to identify (1) the risk-informed activities that have been completed, (2) the risk-informed activities that are currently ongoing, and (3) potential future risk-informed activities that may be pursued. NMSS regulatory applications that may be risk informed include, but are not limited to, rulemaking, guidance development, licensing and certification, and inspection activities for fuel cycle facilities, industrial and medical licensees, site decommissioning, transportation, spent fuel storage, and waste management and disposal.

The Phase 2 effort was completed and a final report was distributed in April 2002 to the NMSS Risk Steering Committee (*Risk-Informing the Materials and Waste Arenas: Phase 2 Report*; April 2002; ADAMS Package ML021020317). The NMSS Risk Steering Committee was briefed on the Phase 2 effort in June 2002.

Separately, but in parallel with Phase 2, the RES and NMSS staff continued to develop and refine safety goals for the materials and waste safety arenas in accordance with an NMSS user-need memorandum. The case studies conducted under Phase 1 demonstrated that safety goals, and qualitative measures of what is safe enough, could be useful or may be necessary in risk-informing specific situations within the materials and waste arenas.

2.3.3 Phase 3

Phase 3 involves the actual modification of the regulatory applications through the implementation of risk-informed activities. Referring to the five-step implementation process described in SECY-99-100, Phase 3 corresponds to steps two through five, described in Section 2.1.1.

NMSS has been actively conducting risk-informed activities on a case-by-case basis, prior to and concurrent with the Phase 1 and Phase 2 activities. Phase 2 compiled the completed and ongoing

activities with potential future activities. Phase 3 will continue with the implementation of these activities, as prioritized through the planning, budgeting, and performance management (PBPM) process, discussed in the following section.

2.3.4 Prioritization of Materials and Waste Safety RIRIP Implementation Activities

In response to the Commission's direction in the January 4, 2001, SRM on the October 2000 version of the RIRIP, the priority rating(s) is listed under each implementation activity. The prioritization processes followed by NMSS, NRR, and RES management, although not the same, use the agency's strategic plan performance goals to prioritize Office activities as part of the budget process. NMSS indicates its priorities by ascribing to each activity a low, medium or high priority. Staff activities are prioritized as they relate to: maintaining safety; improving

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effectiveness, efficiency, and realism; reducing unnecessary regulatory burden; and increasing public confidence.

As with other staff activities, changes in priorities of the staff's risk-informed regulation implementation activities will continue to be made consistent with the PBPM process to reflect changes to the agency budget and priorities.

2.4. DESCRIPTION OF CURRENT INITIATIVES AND ACTIVITIES

Current initiatives and activities to risk-inform the regulatory applications of the materials and waste safety arenas include the following:

Nuclear Material Safety Arena

MS-EER1-1	Develop a Framework for Incorporating Risk Information in the NMSS Regulatory Process
MS-EER1-2	Develop Training Program to Support a Risk-Informed Approach to Implementing NMSS Regulatory Activities
MS-EER1-3	Develop a Guide for Performing Risk Analyses
MS-EER1-4	Develop Safety Goals for the Materials and Waste Arenas
MS-EER1-5	Interagency Jurisdictional Working Group Evaluating the Regulation of Low-level Source Material or Materials Containing less than 0.05 Percent by Weight Concentration Uranium and/or Thorium
MS-EER2-1	Multi-phase Review of the Byproduct Materials Program (Implementation of Phase I and II Recommendations)
MS-MS1-1	Revise Fuel Cycle Oversight Program
MS-MS1-2	Revise Part 72 - Geological and Seismological Characteristics for the Siting and Design of Dry Cask ISFSIs

MS-MS1-3	Exemptions from Licensing and Distribution of Byproduct Material; Licensing and Reporting Requirements
MS-MS1-4	Amend Part 63 to Define a Quantitative Limit, in Terms of Probability of Occurrence, for Unlikely Features, Events, and Processes
MS-MS2-1	Materials Licensing Guidance Consolidation and Revision
MS-MS2-3	Implementation of Part 70 Revision
MS-RB1-1	Revise Part 36: Panoramic Irradiators (PRM-36-01)
MS-RB1-2	Revise Part 34: Radiography (PRM-34-05)

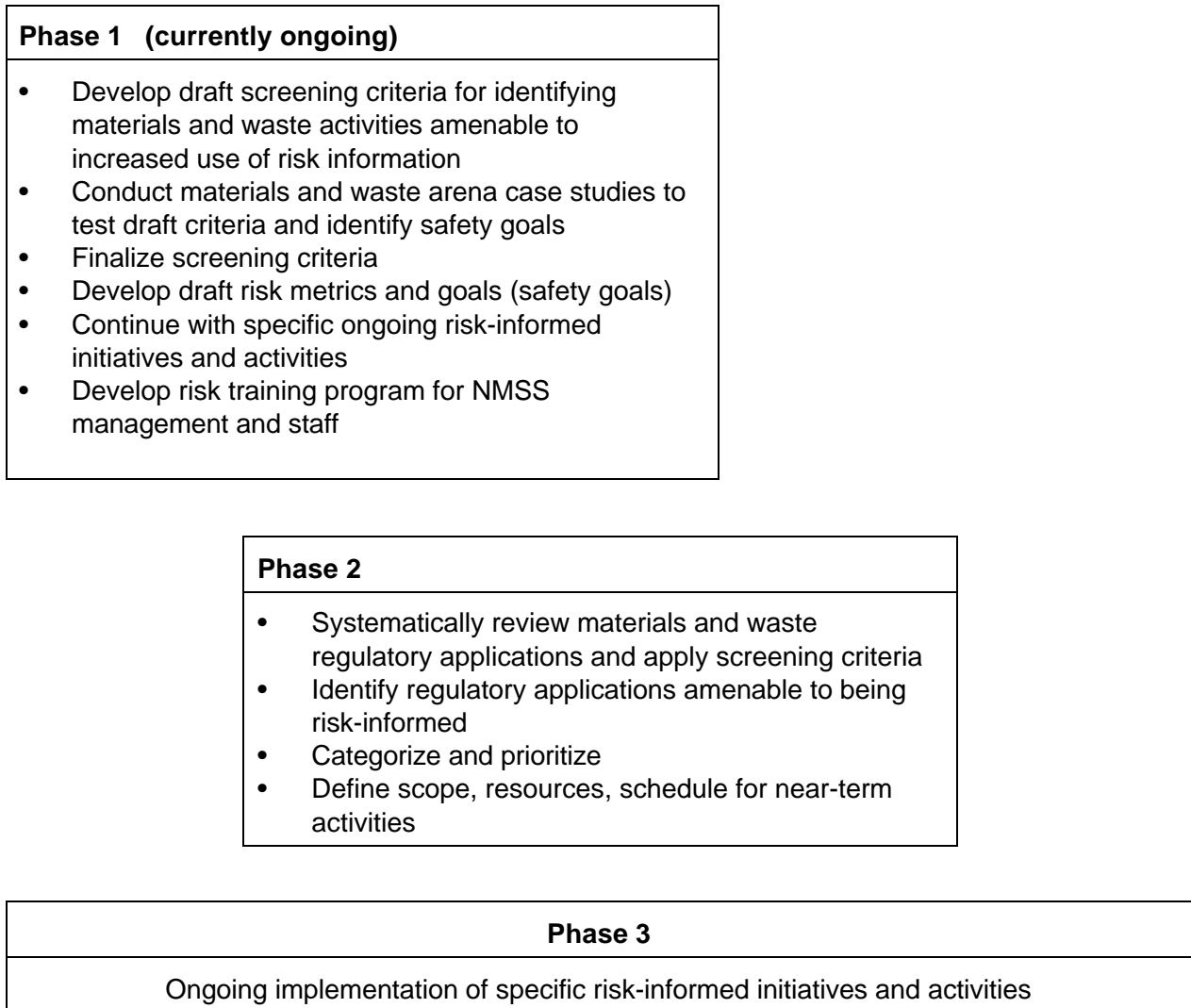
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Nuclear Waste Safety Arena

WS-MS1-1	Probabilistic Risk Assessment of Dry Cask Storage Systems
WS-MS1-2	Incorporate Risk Information into the Decommissioning Regulatory Framework.
WS-MS1-3	Incorporate Risk Information into the High-Level Waste Regulatory Framework.
WS-EER1-1	Cross-Cutting Risk Assessment of Spent Fuel

These initiatives and activities are described in detail on the following pages. The descriptions include applicable project considerations, such as priority, resource allocation, schedule and milestone, interrelationships among activities, and special considerations (e.g., training, stakeholder communications, external dependencies).

Figure 2-1. Three-Phase Plan for Risk-Informing the Materials and Waste Safety Arenas



Implementation Activity: Develop a Framework for Incorporating Risk Information in the NMSS Regulatory Process

(Lead Organization: NMSS/RTG)

Primary Performance Goal: *Make the NRC activities and decisions more effective, efficient, and realistic. (EER)*

Strategy: *We will continue to improve the regulatory framework to increase our effectiveness, efficiency, and realism. (EER1)*

In the SRM for SECY-99-100, dated June 28, 1999, the Commission approved the staff's proposed framework for risk-informed regulation in NMSS. The NMSS Risk Task Group (RTG) has been implementing this framework in three phases. Phase 1 established a systematic method to identify and prioritize candidate regulatory applications that are amenable to expanded use of risk assessment information. RTG conducted eight case studies of NMSS activities to evaluate how risk information has been used or could be used to improve NMSS regulatory processes, including numerous stakeholder meetings, interviews, and site visits. Case study results were integrated with other related risk assessments and were documented in *Risk-Informing the Materials and Waste Arenas: Integration of Case Studies and Related Risk Assessments* (December 2001; addenda February 2002). Through Phase 1, RTG was able to:

- Develop screening considerations for identifying regulatory applications that may be amenable to being risk-informed, and developed a guide for how to use the screening considerations (*Risk Informing the Materials and Waste Arenas: Guidance for Applying the Screening Considerations*, January 2002, ML020300067)
- Establish the feasibility of developing safety goals for the nuclear material and waste arenas, and form a framework for continued development of safety goals
- Evaluate the value of using risk insights and information in the nuclear material and waste arenas
- Identify tools, data and guidance necessary to risk inform NMSS activities

In Phase 2, RTG applied the systematic approach developed in Phase 1 to identify NMSS regulatory applications amenable to being risk-informed. Phase 2 identified potential future risk-informed activities within the scope of each division, as well as activities that cut across divisions. This effort identified areas where organizational effectiveness and efficiencies could be realized with the use of risk information. Phase 2 was initiated in January 2002 and completed in April 2002. Results are documented in *Risk Informing the Materials and Waste Arenas: Phase 2 Report* (April 30, 2002, ML021210081). RTG will meet with the NMSS Risk Steering Committee to discuss the results and receive further guidance on implementing the activities identified in Phase 2.

Phase 3 involves the ongoing implementation of risk informed initiatives and activities, including those identified in Phase 2. Phase 2 cross-cutting activities now in progress (described in subsequent pages) include:

- development of a guide for performing a risk analysis
- development of safety goals (joint effort with RES)
- assessment of the relative safety/risks associated with spent fuel

RTG will consult with the NMSS Divisions to determine whether other Phase 2 activities are beneficial and feasible. Activities will be planned, prioritized and budgeted through the existing NMSS planning, budgeting and performance management (PBPM) process.

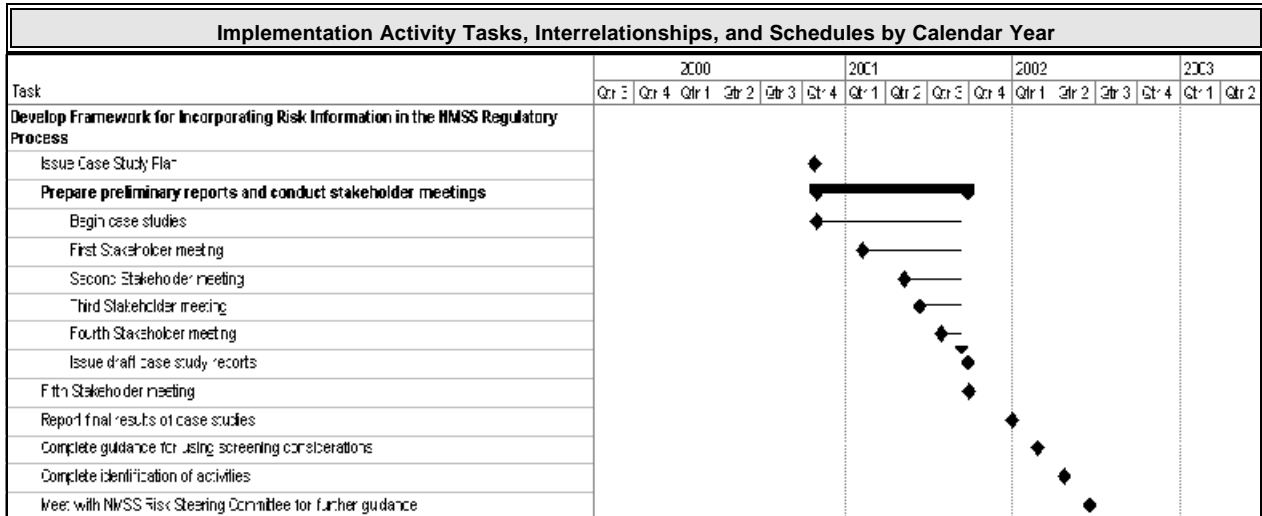
NMSS Priority: Medium

Project Considerations: The NMSS Risk Task Group (RTG) has developed a communications plan in support of its efforts. Additionally, the case-study approach involved numerous public workshops to solicit stakeholder input, in an enhanced participatory process. This activity is inter-related with other agency efforts. RTG is coordinating with other NMSS staff when an ongoing regulatory activity relates to this activity. Also, in FY02 RES and RTG initiated a joint effort to continue development safety goals and other tools, guidance, and data that may be need to risk-inform materials and waste regulatory processes.

Resources Budgeted*		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2002	5	400

*Note: These are the NMSS RTG budgeted resources that are allocated for this RTG activity only. NMSS RTG budgeted resources are also allocated to other activities, such as providing direct support to NMSS divisions for risk-related activities.

Selected Major Milestones and Schedules			
Major Milestones	Original Target Date	Revised Date	Completion Date
Issue case study plan			October 2000
Complete preliminary reports and initial stakeholder meetings			July 2001
Complete final case study reports and consolidated stakeholder meeting	December 2001		October 2001
Report final results of case studies (complete Phase 1)	March 2002		December 2001
Complete guidance for using screening considerations			February 2002
Complete identification of activities (Phase 2)			April 2002
Meet with NMSS Risk Steering Committee for further guidance	June 2002		
Implement risk informed activities (Phase 3)	to be determined on case-by-case basis		



Implementation Activity: Develop Training Program to Support a Risk-Informed Approach to Implementing NMSS Regulatory Activities

(Lead Organization: NMSS/RTG)

Primary Performance Goal: *Make the NRC activities and decisions more effective, efficient, and realistic. (EER)*

Strategies: *We will continue to improve the regulatory framework to increase our effectiveness, efficiency, and realism. (EER1)*

The NMSS Risk Task Group staff has worked with the NRC Technical Training Center (TTC) to develop a series of courses to train NMSS staff on risk activities in the materials and waste arenas. The following Tier I, II, and III risk assessment courses are now offered through the NRC's Professional Development Center:

- P-400 Introduction to Risk Assessment in NMSS
- P-401 Introduction to Risk Assessment in NMSS for Technical Managers
- P-402 Introduction to Risk Assessment in NMSS for Administrative Staff
- P-403 Quantitative Risk Assessment
- P-404 Hazards Analysis for DOE SARs and QRAs, Including Integrated Safety Analysis (ISA)

RTG is also developing a Tier III course on the use of NUREG/CR-6642, "Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems" (P-405). The course will provide a general understanding of the process of developing risk analysis to populate the underlying database of NUREG/CR-6642. Examples will be presented of possible uses of the information in regulatory decision making and will provide an overview of the risk analysis methodology, methods to define systems, uncertainty in human performance assessment, and basic use of the Byproduct Material System Risk database. The dry run for this course will be held in June 2002, to be followed by two courses in Headquarters and one in each Region. The course will continue to be available for self study on CD-ROM.

NMSS Priority: Medium

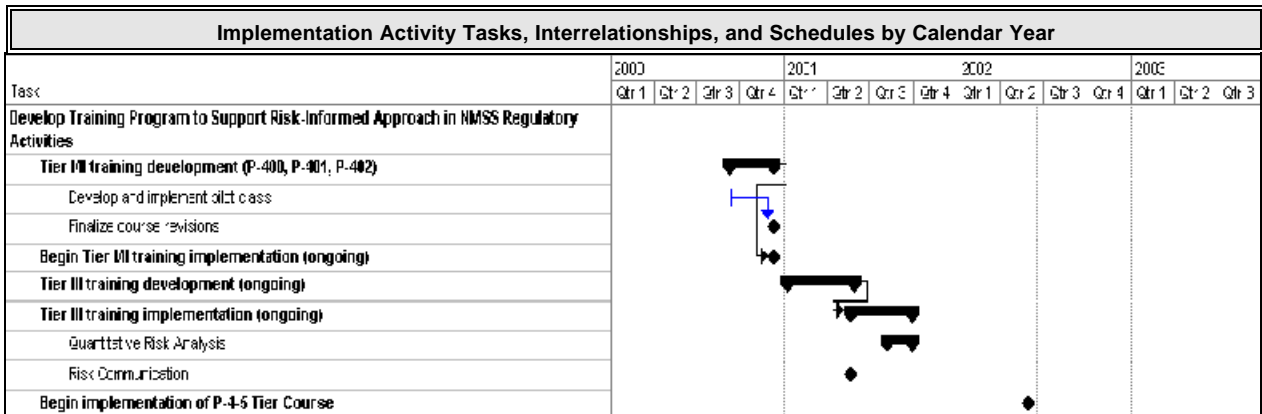
Project Considerations: Evaluation of Tier III training program for risk specialists is ongoing. The staff is working with the TTC to develop the NMSS risk training materials. In developing the Tier III training, all NMSS divisions were consulted to determine needs. Tier III training courses will support the divisions' activities where a need was identified. Staff will also work with external training providers to bring into the Agency existing training courses, where appropriate.

NMSS has developed a communication plan on risk-informing materials and waste regulations . The plan addresses communication with internal stakeholders and the development of the NMSS risk training program.

Resources Budgeted*		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2002	0.2	83

*Note: These are the NMSS RTG budgeted resources that are allocated for this RTG activity only. NMSS RTG budgeted resources are also allocated to other activities, such as providing direct support to NMSS divisions for risk-related activities.

Selected Major Milestones and Schedules			
Major Milestones	Original Target Date	Revised Date	Completion Date
Begin implementation of P-405 Tier III course	June 2002		



Implementation Activity: Develop a Guide for Performing Risk Analyses

(Lead Organization: NMSS/RTG)

Primary Performance Goal: *Make the NRC activities and decisions more effective, efficient, and realistic. (EER)*

Strategy: *We will continue to improve the regulatory framework to increase our effectiveness, efficiency, and realism. (EER1)*

The NMSS Risk Task Group, with support from Brookhaven National Laboratory, is developing a guide for performing a risk analysis. This guidance document will provide a top-level approach to performing a risk assessment in the material and waste arenas. The material and waste arenas present a wide range of technologies for risk assessment. Some technologies are somewhat complex while others are rather straightforward. Thus, this report will survey the range of methodologies that are available and will provide guidance on how to select an evaluation approach in a particular regulatory area. Central to performing a risk assessment is determining the scope and depth of the analysis that would support decision-making related to the regulatory issue or licensing action. In some cases, a simplified risk assessment would be warranted. Particular attention will be given to the products of an analysis, as they will be fundamental to the end uses to which they will be applied.

NMSS Priority: Medium

Project Considerations: This is one of the cross-cutting activities identified in Phase 2.

Resources Budgeted*		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2002	0.3	90

*Note: These are the NMSS RTG budgeted resources that are allocated for this RTG activity only. NMSS RTG budgeted resources are also allocated to other activities, such as providing direct support to NMSS divisions for risk-related activities.

Selected Major Milestones and Schedules			
Major Milestones	Original Target Date	Revised Date	Completion Date
Initiate Task			March 2002
Complete Guide	July 2002		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year																		
Task	2002												2003					
	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar
Develop a Guide for Performing Risk Analyses																		
Complete Guide																		

Implementation Activity: Develop Safety Goals for the Materials and Waste Arenas

(Lead Organization: NMSS/RTG and RES)

Primary Performance Goal: *Make the NRC activities and decisions more effective, efficient, and realistic. (EER)*

Strategy: *We will continue to improve the regulatory framework to increase our effectiveness, efficiency, and realism. (EER1)*

In Phase 1, the NMSS Risk Task Group worked with Brookhaven National Laboratory to begin the process of developing safety goals for the materials and waste arenas. As a result of the case studies, the feasibility of safety goals for the materials and waste arenas was established and a first draft of safety goals was developed. The case studies also yielded the following key insights with regard to safety goals:

- Safety Goals and qualitative measures of what is safe enough could be useful in risk informing specific situations within the materials and waste arenas.
- There are no fundamental impediments to the expansion and broader application of risk information across the spectrum of NMSS-regulated activities.
- Risk-information can be valuable as an additional input to risk management decisions that NMSS must make.
- Risk information can help make the existing regulatory framework more rational.
- An integrated and balanced risk management program would recognize both public and worker risks as well as radiological and non-radiological risks at regulated facilities.

The Risk Task Group initiated a joint effort with RES to continue developing materials and waste safety goals and risk metrics, and to develop other tools, methods, data, guidance and standards necessary for implementing risk-informed approaches in NMSS. A User Need Memo was sent to RES on January 30, 2002. In response to the User Need, RES has initiated a contract with Brookhaven National Laboratory to continue to support risk-informed initiatives for nuclear materials and waste.

NMSS Priority: Medium

Project Considerations: Safety goal development is one of the cross-cutting activities identified in Phase 2. The NMSS Risk Task Group (RTG) has developed a communications plan in support of its efforts. In accordance with the SRM to SECY-99-100, safety goals will be developed through an enhanced participatory process.

Resources Budgeted*		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2002	0.5 (NMSS) 1 (RES)	300 (RES)

*Note: These are the NMSS RTG budgeted resources that are allocated for this RTG activity only. NMSS RTG budgeted resources are also allocated to other activities, such as providing direct support to NMSS divisions for risk-related activities.

Selected Major Milestones and Schedules			
Major Milestones	Original Target Date	Revised Date	Completion Date
NMSS user need memo to RES			January 2002
RES response to user need			February 2002
RES Initiate contract with BNL			March 2002
RES/NMSS/BNL Safety Goal Meeting	June 2002		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year																			
Task	2002												2003						
	Aug	Seq	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Seq	Oct	Nov	Dec	Jan	Feb
Develop safety goals for the materials and waste arenas.																			
NMSS User need memo to RES						◆													
RES response to user need							◆												
RES Initiate contract with BNL								◆											
RES/NMSS/BNL Safety Goal Meeting																			◆

Implementation Activity: Interagency Jurisdictional Working Group Evaluating the Regulation of Low-level Source Material or Materials Containing less than 0.05 Percent by Weight Concentration Uranium and/or Thorium

(Lead Organization: NMSS/IMNS)

Primary Performance Goal: *Make the NRC activities and decisions more effective, efficient and realistic (EER)*

Strategy: *We will continue to improve the regulatory framework to increase our effectiveness, efficiency, and realism.*

The Part 40 Jurisdictional Working Group (Working Group) includes a representative from various Federal agencies and a representative from the States (representing the Organization of Agreement States and the Conference of Radiation Control Program Directors). The Working Group evaluated current jurisdictional authorities for the regulation of low-level source material or materials containing less than 0.05 percent by weight concentration uranium or thorium. The Working Group has found that most materials/processes are regulated by some regulatory agency. The Working Group analyzed available technical data to assist its assessment of risks to workers and the public from uranium and thorium below 0.05 percent by weight concentration, including a review of the results of NUREG-1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Material." The Working Group concluded the results in NUREG-1717 were based on conservative assumptions, and that the doses are actually much lower than those given in the NUREG. However, there may be other scenarios, related to other industries that were not evaluated, that could result in exposures to workers and members of the public. As such, the Working Group believes that some oversight of the material subject to this exemption is needed. The recommendations of the Working Group are being submitted to the Commission in a separate paper in early summer, 2002.

NMSS Priority: High

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2002	2.0	0.0

Selected Major Milestones and Schedules			
Major Milestones	Original Target Date	Revised Date	Completion Date
Recommendations from the Part 40 Jurisdictional Working Group to the Commission	June 2002		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year													
Task	2002												
	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep
Evaluation of regulation of low-level source material containing less than 0.05 percent U and/or Th.													
Recommendations from the Part 40 Jurisdictional Working Group to the Commission													

**Implementation Activity: Multi-phase Review of the Byproduct Materials Program
(Implementation of Phase I and II Recommendations)**

(Lead Organization: NMSS/IMNS)

Primary Performance Goal: *Make the NRC activities and decisions more effective, efficient, and realistic. (EER)*

Strategy: *We will identify, prioritize, and modify processes based on effectiveness reviews to maximize opportunities to improve those processes. (EER2)*

The staff used the risk information in NUREG/CR-6642, along with supplemental records from the underlying database, in its review of the "Mallinckrodt Lessons Learned" and the possible subsequent revision of the Inspection and Licensing Guidance. Previously NMSS had established two task groups (Phase I and Phase II) to review the materials licensing and inspection program and provide recommendations. Phase I reviewed findings of the Mallinckrodt inspections in Region I and Region III that involved overexposures to develop lessons learned for licensing and inspection, regulatory changes, and NRC/State jurisdiction. Phase II reviewed the overall materials program and recommended changes to the existing licensing and inspection program to improve effectiveness and efficiency. Both task groups have used the four agency performance goals: maintaining safety; reducing unnecessary regulatory burden; enhancing public confidence; and efficiency, effectiveness, and realism.

The staff developed an action plan for the Phase I and II recommendations. Items were identified for short-term action, long-term action, or information technology action. The greatest savings were identified for revision of Inspection Manual Chapter 2800, Materials Inspection Program (IMC 2800). The staff initiated a 12-month pilot program (Temporary Instruction 2800/033) to be implemented by the Regional offices and also invited the Agreement States to participate. The purposes of the pilot program are to gain effectiveness and efficiency through a more risk-informed and performance-based approach for routine inspections that are completed by the Regional inspection staff.

NMSS Priority: High

Project Considerations: The staff identified 20 recommendations from Phase I for specific changes to IMC 2800 and various inspection procedures. The Phase II review endorsed the majority of the Phase I recommendations. In addition, Phase II provided 24 recommendations for the broad, programmatic review of the materials program. To implement the Phase II recommendations and obtain savings for the materials inspection program, the staff developed a 12-month pilot program to streamline administrative processes described in IMC 2800. Risk information was used to identify certain categories of licenses for which the inspection intervals have been lengthened. Consequently, fewer routine inspections will be scheduled because some inspections that would have been completed during the next 12 months will be rescheduled for future years. However, the current practice of reducing the inspection interval for an individual licensee exhibiting a trend of poor performance will continue. Other revisions to IMC 2800 are consistent with a more performance-based inspection style, including the manner in which inspectors prepare for and document the results of routine inspections. There are 11 inspection procedures (IP 87110 through IP 87120) associated with IMC 2800 which are being revised to reflect the revised IMC 2800 during the pilot program, including four procedures being revised to reflect the final rule changes to 10 CFR Part 35, effective October 24, 2002.

To improve effectiveness and efficiency for the licensing process, the staff published an article in the NMSS Licensee Newsletter to encourage use of the NUREG-1556 series of licensing guidance documents and developed supplemental, interim guidance which streamlines the Technical Assistance Request process. The event evaluation process for the materials program was revised to provide a more performance-based approach.

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2002	1.5	0

Selected Major Milestones and Schedules			
Major Milestones	Original Target Date	Revised Date	Completion Date
Final Phase I group report	November 2000		November 2000
Final Phase II group report	August 2001		August 2001
Complete revision of inspection procedures for Part 35	Summer 2002		
IMC 2800 Revised	July 2003		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year												
Task	2001				2002				2003			
	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	
Multi-Phase Review of the Byproduct Materials Program												
Phase I												
Phase II												
Phase I working group initiated												
Final Phase I group report												
Complete revision of inspection procedures for Part 35												
IMC 2800 Revised												

Implementation Activity: Revise Fuel Cycle Oversight Program

(Lead Organization: NMSS/FCSS)

Primary Performance Goal: *Maintain safety, protection of the environment, and the common defense and security. (MS)*

Strategy: *We will continue to improve the regulatory framework to increase our focus on safety and safeguards, including incremental use of risk-informed and, where appropriate, less prescriptive performance-based regulatory approaches to maintain safety. (MS1)*

NMSS is establishing the framework for making the fuel cycle oversight program more risk-informed and performance-based. The revised oversight program will include risk-informed inspections, evaluation of the risk significance of facility events and inspection findings, more scrutable and predictable enforcement and assessment of licensee performance, and enhanced communications with stakeholders. The revised oversight program will build on the risk-informed regulations associated with the new Part 70 rulemaking and will focus on the results of licensees' ISAs. As a result, the staff expects that the fuel cycle facility oversight process will evolve in a more risk-informed direction over the next several years, commensurate with the implementation of the Part 70 revisions.

NMSS Priority: Medium

Project Considerations: This activity is dependent on other initiatives, including the implementation of the recent revisions to Part 70, lessons learned from NRR's implementation of the Reactor Oversight Process, and lessons learned from the activities of NMSS's Risk Task Group.

Some training will be needed to familiarize staff and management on process changes.

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2002	1.0	0

Selected Major Milestones and Schedules			
Major Milestones	Original Target Date	Revised Date	Completion Date
Implement revisions to IMC 2600	October 2001	October 2002	
Implement revisions to IMC 2604	October 2001	June 2002	

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year																			
Task	2002				2003				2004				2005						
	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	
Revisions to Fuel Cycle Oversight Program																			
Implement revisions to IMC 2600				◆															
Implement revisions to IMC 2604			◆																

Implementation Activity: **Revise Part 72 - Geological and Seismological Characteristics for the Siting and Design of Dry Cask ISFSIs**

(Lead Organization: NMSS/IMNS)

Primary Performance Goal: *Maintain safety, protection of the environment, and the common defense and security. (MS)*

Strategy: *We will continue to improve the regulatory framework to increase our focus on safety and safeguards, including incremental use of risk-informed and, where appropriate, less prescriptive performance-based regulatory approaches to maintain safety. (MS1)*

The staff proposes to use a risk-informed approach in the Modified Rulemaking Plan, "Geological and Seismological Characteristics for the Siting and Design of Dry Cask ISFSIs". The plan will amend certain sections in 10 CFR Part 72 dealing with seismic siting and design criteria for dry cask independent spent fuel storage installations (ISFSIs). The staff proposes to lower the design earthquake to a level that is commensurate with the lower risk associated with an ISFSI facility.

NMSS Priority: High

Project Considerations: While no special training will be developed to complete this activity, implementation of this rulemaking may require additional training on the use of probabilistic risk analysis (PRA).

This activity is related to an ongoing RES activity, Dry Cask Storage Probabilistic Risk Assessment, that was requested by the SFPO (see activity WS-MS1-1). The RES effort involves a pilot PRA for a dry cask storage system and is expected to provide additional quantitative support for the design earthquake level proposed in the rulemaking. Note that the revised milestone dates reflect the revised schedule proposed in the modified rulemaking plan.

NMSS has developed a communication plan for the high-level waste program (ADAMS Accession #ML003753322), which explicitly addresses spent fuel storage and ISFSIs.

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2002	2.0	167

Selected Major Milestones and Schedules			
Major Milestones	Original Target Date	Revised Date	Completion Date
Proposed rule to Commission (SECY-02-0043)			March 13, 2002
Final rule to EDO	7 months following end of public comment period	4.5 months following end of public comment period	

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year																								
Task	2002												2003											
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun						
Revise Part 72 -- Geological and Seismological Characteristics for the Siting and Design of Dry Cask ISFSIs																								
Proposed rule to Commission (SECY-02-0043)																								

Implementation Activity: Exemptions from Licensing and Distribution of Byproduct Material; Licensing and Reporting Requirements

(Lead Organization: NMSS/IMNS)

Primary Performance Goal: *Maintain safety, protection of the environment, and the common defense and security. (MS) All four performance goals will be advanced.*

Strategy: *We will continue to improve the regulatory framework to increase our focus on safety and safeguards, including incremental use of risk-informed and, where appropriate, less prescriptive performance-based regulatory approaches to maintain safety. (MS1)*

The staff has been conducting a systematic reevaluation of the exemptions from licensing in Parts 30 and 40, which govern the use of byproduct and source materials. A major part of the effort has been an assessment of potential and likely doses to workers and public under these exemptions. The assessment of doses associated with most of these exemptions was published as NUREG-1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Material," June 2001. NUREG-1717 also includes dose assessments for certain devices currently used under a general or specific license that had been identified as candidates for use under exemption. The results of this study have been considered in the development of a draft rulemaking plan, "Exemptions from Licensing and Distribution of Byproduct Material; Licensing and Reporting Requirements," which is due to the Commission the end of June. The rulemaking would revise the exemptions from licensing in Part 30 and the requirements for exempt distribution in Part 32 to make the controls more commensurate with the potential doses associated with the various exemptions. It would also establish one or more new exemptions to reduce regulatory burden related to the use of some products with low associated risks and make the regulations more flexible, user-friendly, and performance-based for requirements for distributors of generally licensed devices. The results of the systematic reevaluation of the exemptions with respect to the regulation of source material will be addressed in a separate activity for which a rulemaking plan is before the Commission: SECY-01-0072, Draft Rulemaking Plan: Distribution of Source Material to Exempt Persons and to General Licensees and Revision of 10 CFR 40.22 General License, April 25, 2001.

NMSS Priority: High

Project Considerations: The Exemptions Working Group evaluated the requirements related to exemptions and certain generally licensed devices, identified a number of issues for consideration in rulemaking, and developed recommendations for improving the regulatory framework for both the Part 30 exemptions from licensing for byproduct material and those in Part 40 for source material. Recommendations for Part 40 were coordinated with the Part 40 Rulemaking Working Group.

The Working Group includes members from NMSS, Region IV, OGC, OSTP, RES, and OE.

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2002	0.7	15

Selected Major Milestones and Schedules			
Major Milestones	Original Target Date	Revised Date	Completion Date
Recommendations from the Systematic Assessment of Exemptions and the Rulemaking Plan to Commission	June 2002		
Proposed rule to EDO	18 months after SRM on rulemaking plan		
Final rule to EDO	12 months after proposed rule published		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year												
Task Name	2002				2003				2004			
	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	
Exemptions from licensing and distribution of byproduct material: licensing and reporting requirements.												
Recommendations from the Systematic Assessment of Exemptions and Rulemaking Plan to Commission												

Implementation Activity: Amend Part 63 to Define a Quantitative Limit, in Terms of Probability of Occurrence, for Unlikely Features, Events, and Processes

(Lead Organization: NMSS/IMNS)

Primary Performance Goal: *Maintain safety, protection of the environment, and the common defense and security. (MS)*

Strategy: *We will continue to improve the regulatory framework to increase our focus on safety, including incremental use of risk-informed and, where appropriate, less prescriptive performance-based regulatory approaches to maintain safety. (MS1)*

The NMSS rulemaking staff is engaged in rulemaking to amend the regulations governing the disposal of high-level radioactive wastes in a potential geologic repository at Yucca Mountain, Nevada, to define the term “unlikely” in quantitative terms. That is, it would be defined as a range of numerical values for use in determining whether a feature, event, or process (FEP) or sequence of events and processes should be excluded from certain required assessments. The staff is taking this action to clarify how it plans to implement two of the final environmental standards for Yucca Mountain issued by the U.S. Environmental Protection Agency (EPA). Specifically, EPA’s final standards require the exclusion of “unlikely” FEPs, or sequences of events and processes, from the required assessments for the human intrusion and ground-water protection standards. In accordance with the Energy Policy Act of 1992, the NRC has adopted EPA’s final standards in its recently published technical requirements for a potential geologic repository at Yucca Mountain.

The NRC published a proposed rule, “10 CFR Part 63: Specification of a Probability for Unlikely Features, Processes, and Events”, on January 25, 2002 (67 FR 3628), and requested public comments.

NMSS Priority: High

Project Considerations: In assessing compliance with both the human intrusion standard and ground-water protection standards, 10 CFR 63.342 provides that unlikely FEPs, or sequences of events and processes, shall be excluded "...upon prior Commission approval for the probability limit used for unlikely FEPs. "Although the Commission could review and approve a probability limit in the context of its review of a potential DOE license application, it is proposing to set this limit in advance, through the rulemaking process, so that it will have the advantage of public views on this question, and so that DOE, interested participants, and the public will have knowledge, before the license application, of what probability the Commission would find acceptable.

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2002	0.8	0.0

Selected Major Milestones and Schedules			
Major Milestones	Original Target Date	Revised Date	Completion Date
Issue proposed rule	January 2002		January 2002
Issue final rule	September 2002		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year																
Task Name	2002															
	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Amend Part 63 to define a quantitative limit to unlikely features, events and processes																
Issue proposed rule					◆											
Issue final rule																◆

Implementation Activity: Materials Licensing Guidance Consolidation and Revision

(Lead Organization: NMSS/IMNS)

Primary Performance Goal: *Maintain safety, protection of the environment, and the common defense and security. (MS)*

Strategy: *We will continue authorizing licensee activities only after determining that these proposed activities will be conducted consistent with the regulatory framework. (MS2)*

In FY 01 the Division of Industrial and Medical Nuclear Safety (IMNS) completed the first phase of licensing guidance consolidation with the final publication of twenty volumes of "Consolidated Guidance about Materials Licenses" (NUREG-1556).

The individual volumes of NUREG-1556 will be reviewed every three years and revised, if needed. The recommendations from the Phase II report (issued August 2001) from the Multi-phase Review of the Byproduct Materials Program activity will be incorporated. (Phase II is a broad review of the entire materials program, while Phase I focused on lesson learned from the overexposure events at the Mallinckrodt facility and a radiopharmacy.) The future revisions will include the integration of risk information contained in NUREG/CR-6642, "Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems."

The following volumes of NUREG-1556 are scheduled for completion/review/revision in FY03 and FY04.

Vol. 2	Program-Specific Guidance About Radiography Licenses
Vol. 3	Applications for Sealed Source and Device Evaluation and Registration
Vol. 4	Program-Specific Guidance About Fixed Gauge Licenses
Vol. 5	Program-Specific Guidance about Self-Shielded Irradiators
Vol. 8	Program-Specific Guidance about Exempt Distribution Licenses
Vol. 9	Program-Specific Guidance About Medical Use Licenses

In FY 02 the IMNS is proceeding with licensing and inspection guidance to make it more risk-informed and performance based to fulfill a February 2002 commitment to the Congress. A second draft of licensing guidance contained in NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses; Program-Specific Guidance About Medical Use Licenses," was published in March 2002. This document will provide guidance to the public and staff for licensing under 10 CFR Part 35, "Medical Use of Byproduct Material." Part 35 was issued on April 24, 2002, with an effective date of October 24, 2002.

Revision of guidance contained in drafts of NUREG-1556 Vol. 9 and inspection procedures will be completed in time for use before the effective date of Part 35. Training will also be conducted for licensing and inspection staff during the Summer of 2002; this training will also be made available to staff in Agreement States.

NMSS Priority: Priority will be established based on the recommendations from the Phase II report of the Multi-phase Review of the Byproduct Materials Program activity and rulemakings.

Project Considerations: If revisions are needed other than administrative, the NUREG will be published for public comments. This implementing activity is related to the Multi-phase Review of the Byproduct Materials Program activity and NUREG/CR 6642. Vol. 9 will be revised based on comments received during public meetings and in writing.

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2002	1.8	330

Selected Major Milestones and Schedules			
Major Milestones	Original Target Date	Revised Date	Completion Date
Complete Vol. 9	Summer 2002		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year													
Task	2000				2001				2002				
	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Materials Licensing Guidance Consolidation and Revision													
Complete Volume 9													

Implementation Activity: Implementation of Part 70 Revision

(Lead Organization: NMSS/FCSS)

Primary Performance Goal: *Maintain safety, protection of the environment, and the common defense and security. (MS)*

Strategies: *We will continue authorizing licensee activities only after determining that these proposed activities will be conducted consistent with the regulatory framework. (MS2)*

On September 18, 2000 (65 FR 56211), the Commission published a final rule (Part 70) amending its regulations governing the domestic licensing of special nuclear material (SNM) for certain licensees authorized to possess a critical mass of SNM. The Commission's action was in response to a "Petition for Rulemaking," PRM-70-7, submitted by the Nuclear Energy Institute, which was published on November 26, 1996 (61 FR 60057). The majority of the modifications to Part 70 are included in a new Subpart H, "Additional Requirements for Certain Licensees Authorized to Possess a Critical Mass of Special Nuclear Material." These modifications were made to increase confidence in the margin of safety at the facilities affected by the rule, while reducing unnecessary regulatory burden, where appropriate.

In developing the rule, the Commission sought to achieve its objectives through a risk-informed and performance-based regulatory approach by requiring licensees to (1) perform an integrated safety analysis (ISA) to identify significant potential accidents at the facility and the items relied on for safety; and (2) implement measures to ensure that the items relied on for safety are available and reliable to perform their functions when needed.

In December 2001, FCSS staff, along with the RTG and Part 70 stakeholders, finalized a Standard Review Plan to implement the requirements of Subpart H. This guidance document, which was published in March 2002, will assist the licensees in conducting ISAs and the staff in reviewing ISA documentation. The NRC staff has also developed, and is in the process of developing, other guidance documents related to Subpart H.

The staff has begun conducting ISA reviews for individual amendment requests. The staff anticipates conducting more detailed site-wide ISA documentation reviews in FY03, FY04, and FY05 for six operating uranium fuel fabrication facilities.

NMSS Priority: Medium

Project Considerations: The NMSS Risk Task Group (RTG) conducted two training sessions to guide ISA reviewers through Subpart H of 10 CFR Part 70 and Appendix A of Chapter 3 of the SRP which provides a method for the licensees for conducting ISAs and preparing ISA Summaries. No additional classroom training is anticipated in FY 2002. Continued guidance from the RTG, as the initial ISA reviews are conducted, will prove to be beneficial. This activity is related to enhancing external communications in that several stakeholders are involved, including NEI and the licensees.

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2002	2.4	0.0

Selected Major Milestones and Schedules			
Major Milestones	Original Target Date	Revised Date	Completion Date
Finalize Standard Review Plan for 10 CFR Part 70, Subpart H			December 2001
Publish Standard Review Plan for 10 CFR Part 70, Subpart H			March 2002
Review ISA documentation	as received from licensees		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year																									
Task Name	2002												2003												
	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar						
Finalize Standard Review Plan for 10 CFR Part 70, Subpart H					◆																				
Publish Standard Review Plan for 10 CFR Part 70, Subpart H								◆																	

Implementation Activity: Revise Part 36: Panoramic Irradiators (PRM-36-01)

(Lead Organization: NMSS/IMNS)

Primary Performance Goal: *Reduce unnecessary regulatory burden on stakeholders. (RB)*

Strategies: *We will continue to improve our regulatory framework in order to reduce unnecessary regulatory burden. (RB1)*

We will improve and execute our programs and processes in ways that reduce unnecessary costs to our stakeholders. (RB2)

The staff used the risk information in "Risk Analysis and Evaluation of Regulatory Options for Nuclear Byproduct Material Systems" (NUREG/CR-6642) in its analysis of the "Petition for Rulemaking," PRM-36-1, which requests modification of 10 CFR 36.65(a) and (b). These regulations describe how an irradiator must be attended to allow for the operation of a panoramic irradiator with qualified operators on site. The staff, with the assistance of a contractor, conducted a specific risk assessment associated with the presence of an onsite operator by using the models and information found in NUREG/CR-6642. In addition, a survey was conducted on historical irradiator accidents worldwide that may have been attributed to the presence or lack of an onsite operator. Based on the results of the risk assessment and the findings of the survey, the staff prepared a draft rulemaking plan to amend the regulation using a risk-informed approach. *Due to the 9/11 event, the rulemaking activity was put on hold pending an NRC-wide vulnerability evaluation.*

NMSS Priority: Medium

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2002	0.3	0.0

Selected Major Milestones and Schedules			
Major Milestones	Original Target Date	Revised Date	Completion Date
Draft Rulemaking plan to EDO	August 2001	September 2001	September 2001

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year																								
Task	2001												2002											
	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov				
Revise Part 36: Panoramic Irradiators (PRM-36-01)																								
Rulemaking plan to EDO																								

Implementation Activity: Revise Part 34: Radiography (PRM-34-05)

(Lead Organization: NMSS/IMNS)

Primary Performance Goal: *Reduce unnecessary regulatory burden on stakeholders. (RB)*

Strategies: *We will continue to improve our regulatory framework in order to reduce unnecessary regulatory burden. (RB1)*

We will improve and execute our programs and processes in ways that reduce unnecessary costs to our stakeholders. (RB2)

The staff used the risk information in NUREG/CR-6642 in its analysis of the "Petition for Rulemaking," PRM-34-05, which requests deletion of the term "associated equipment" from 10 CFR Part 34. This would essentially remove associated equipment from consideration under 10 CFR 32.210(c) and 30.32(g), which require radiation safety evaluation and registration of sealed sources and devices. With the assistance of a contractor, the staff assessed the risk of using associated equipment that has not been evaluated for design and performance criteria as components in gamma radiography systems. The staff is using the findings to prepare a rulemaking plan for Commission consideration.

NMSS Priority: High

Project Considerations: The staff recommends no rulemaking because the existing requirements are appropriate. However, the staff recommends that in order to reduce unnecessary regulatory burden for licensees, the NRC, and the Agreement States, NRC guidance should be revised to clarify that safety critical components of an industrial radiography system must be evaluated under the registration process for sealed sources and devices, but associated equipment need not be registered. The proposed denial of the petition will emphasize the risk-informed and more performance based approach.

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2002	0.3	0.0

Selected Major Milestones and Schedules			
Major Milestones	Original Target Date	Revised Date	Completion Date
Obtain risk analysis	July 2001		July 2001
SECY Paper, including rulemaking plan package, with a proposed denial of PRM-34-05	July 2002		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year																
Task	2000				2001				2002				2003			
	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3
Revise Part 34: Radiography (PRM-34-05)																
Obtain risk analysis																
Develop rulemaking plan																
SECY paper, including rulemaking plan package																

Implementation Activity: Probabilistic Risk Assessment of Dry Cask Storage Systems

(Lead Organizations: NMSS/SFPO and RES)

Primary Performance Goal: *Maintain safety, protection of the environment, and the common defense and security. (MS)*

Strategy: *We will continue developing a regulatory framework to increase our focus on safety, including the incremental use of risk-informed and, where appropriate, less prescriptive performance-based regulatory approaches to maintain safety. (MS1)*

The staff has initiated a spent fuel dry storage cask probabilistic risk assessment (PRA). (Phase I) This project will develop a method for performing a PRA for spent fuel dry cask storage systems and perform the first NRC dry cask storage system “pilot” PRA. Risk insights from the study will be used to support the staff’s decision-making activities and implementing programs involving dry cask storage. (Phase II) The “pilot” PRA will be updated, as appropriate, to aid risk-informing NRC’s inspection programs for dry storage of spent nuclear fuel.

NMSS Priority: High

RES Priority: 7.2

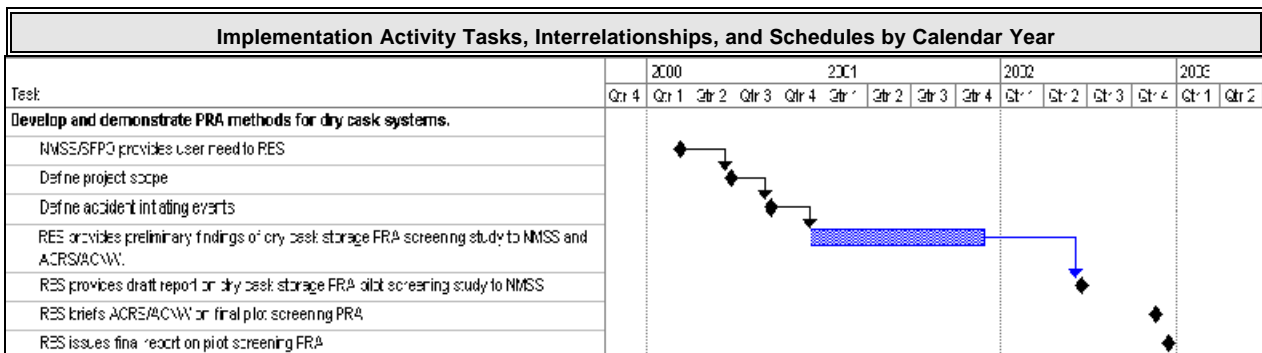
Project Considerations: This activity requires technical assistance and development of analytical and calculational methods. Completion of the analyses will help SFPO explain the basis for review methodology and design acceptance criteria.

SFPO staff are taking PRA training presently offered through the TTC. Additionally, selected technical staff are being trained on the specific codes employed in conducting this activity.

NMSS has developed a communication plan for the high level waste program (ADAMS Accession #ML003753322) which explicitly addresses dry cask storage systems.

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2002	1.8 (NMSS) 3.4 (RES)	0 (NMSS) 1100 (RES)

Selected Major Milestones and Schedules			
Major Milestones	Original Target Date	Revised Date	Completion Date
Define project scope and initiate pilot screening PRA			June 2000
Conduct briefing on preliminary integrated risk results	November 2001		November 2001
Complete pilot screening PRA and issue a draft report on integrated risk results	April 2002	June 2002	June 2002
Finalize pilot screening PRA and issue report	December 2002		
Conduct briefing on final pilot screening PRA for ACRS/ACNW	November 2002		



Implementation Activity: Incorporate Risk Information into the Decommissioning Regulatory Framework.

(Lead Organization: NMSS/DWM)

Primary Performance Goal: *Maintain safety, protection of the environment, and the common defense and security. (MS)*

Strategy: *We will continue to improve the regulatory framework to increase our focus on safety, including the incremental use of risk-informed and, where appropriate, less prescriptive performance-based regulatory approaches to maintain safety. (MS1)*

In April 2001 staff identified several actions being undertaken by the Regions to improve the efficiency of inspections at sites undergoing decommissioning. These actions include focusing resources at sites actively being decommissioned, linking inspections to licensee's on-site activities (to allow inspectors to make side-by-side observations and measurements during licensee's surveys) and limiting the scope and depth of inspections to examining key decommissioning activities. Focusing inspections to improve efficiency should also result in a more risk-oriented inspection approach, as inspections will focus on those decommissioning activities that could increase risks to workers, the public or the environment.

In 2001, the NMSS Division of Waste Management completed an evaluation of a decommissioning pilot program which tested a performance-based decommissioning review process. The pilot program focused on residual contamination goals and allowed participants to decommission their sites without obtaining approved decommissioning plans. The pilot program started with five participants. Participants that completed the program indicated that their experiences were positive and that the revised process resulted in schedule and cost savings. Staff evaluated participant information and determined that, while the pilot was successful for the participating sites, adequate flexibility existed in the current regulations to allow other licensees to gain the same benefits as those in the pilot program and, as such, recommended to the Commission that the program not be continued.

NMSS is currently reviewing all decommissioning policy and guidance documents for:

1. Efficiency, use of a streamlined approach, and user-friendliness of the processes described in the documents; and
2. The use of risk-informed, performance-based (RIPB) techniques, or risk-informed, less-prescriptive techniques, in the processes described in the documents.

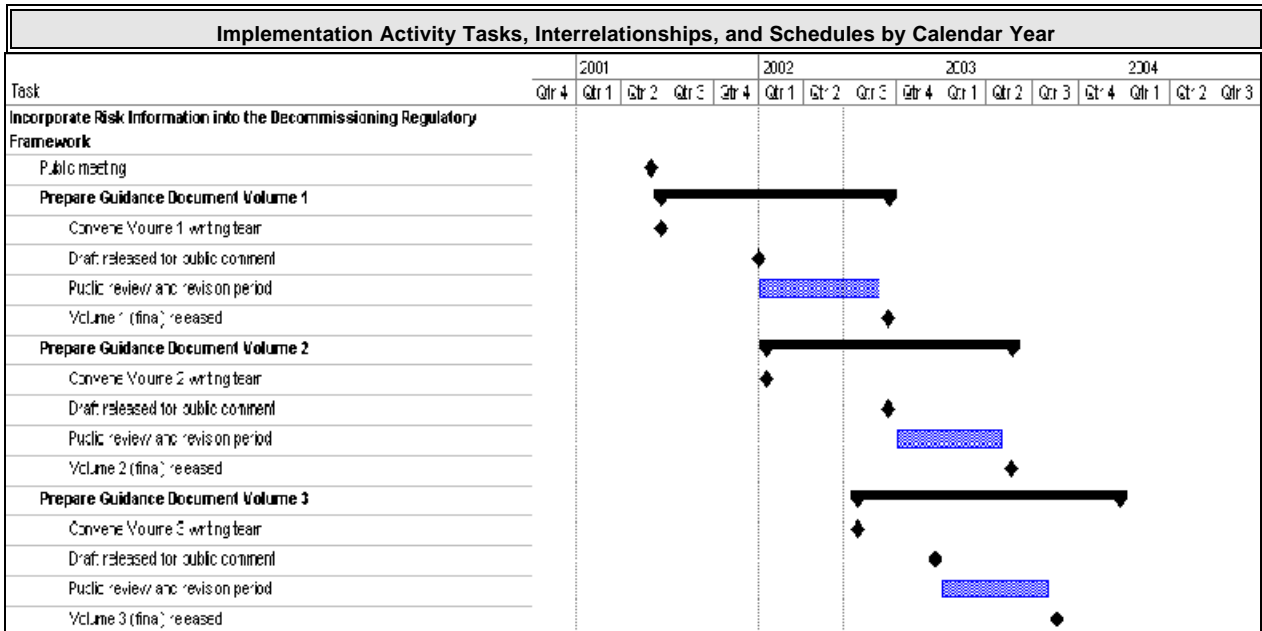
The goal of the policy and guidance review is to apply RIPB techniques to NMSS's decommissioning process as much as possible. For this, NMSS will use the guidance and experience developed through (1) the "Business Project Redesign" policy and guidance review and consolidation process for byproduct material licensing (NUREG-1556 series); (2) the experience gained with risk-informing the dose modeling guidance while working on the NMSS Decommissioning SRP (NUREG-1727); and (3) the ongoing evaluation of new and different approaches to the decommissioning review process that was stipulated in the SRM on decommissioning non-reactor facilities (DSI-9).

NMSS Priority: Low

Project Considerations: Consolidation of existing guidance will enhance staff and licensees ability to comply with NRC's decommissioning requirements and provide a clearer basis for the requirements. Convening the various writing teams is considered to be a critical path activity.

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2002	2.7	65

Selected Major Milestones and Schedules			
Major Milestones	Original Target Date	Revised Date	Completion Date
Hold a Public Meeting to discuss the project	June 2001	June 2001	June 2001
Convene the Volume 1 writing team	June 2001	June 2001	June 2001
Volume 1 (draft) released for public comment	November 2001	January 2002	January 2002
Volume 1 (final) released	July 2002	September 2002	
Convene the Volume 2 writing team	January 2002	January 2002	January 2002
Volume 2 (draft) released for public comment	June 2002	September 2002	
Volume 2 (final) released	January 2003	May 2003	
Convene the Volume 3 writing team	July 2002	July 2002	
Volume 3 (draft) released for public comment	December 2002	December 2002	
Volume 3 (final) released	July 2003	August 2003	



Implementation Activity: Incorporate Risk Information into the High-Level Waste Regulatory Framework.

(Lead Organization: NMSS/DWM)

Primary Performance Goal: *Maintain safety, protection of the environment, and the common defense and security.*

Strategy: *We will continue to improve the regulatory framework to increase our focus on safety, including incremental use of risk-informed and, where appropriate, less prescriptive performance-based regulatory approaches to maintain safety. (MS1)*

In November 2001, the staff published in the Federal Register the final Yucca Mountain risk-informed, performance-based rule (10 CFR Part 63). The final rule focused on implementing a risk-informed performance-based approach based on the final Environmental Protection Agency (EPA) high-level waste standards (40 CFR Part 197).

In March 2002, Revision 2 of the Yucca Mountain Review Plan was completed and provided to public for comment. The staff revised the Yucca Mountain Review Plan Revision 1 to incorporate the final 10 CFR Part 63 requirements in a risk-informed, performance-based manner. The review plan provides guidance to staff on implementing the risk-informed, performance-based regulations of 10 CFR Part 63. This guidance will ensure that licensing reviews are risk-informed and the proper level of effort is focused on areas important to the findings.

The staff developed preliminary sufficiency comments on the Department of Energy (DOE) Site Recommendation proposal based upon the risk-informed framework. The staff provided the comments to the Commission and the DOE as part of their Site Recommendation. The comments should enhance any potential DOE application for a license for a repository.

The staff are conducting a risk insights initiative to ensure that the staff are focusing on the most important issues during the issue resolution process with the DOE. This communication and integration exercise includes all technical and performance assessment staff involved in the high-level waste program at NRC and at the Center for Nuclear Waste Regulatory Analyses. As a result of a series of facilitated meetings with each key technical issue team the staff came to a better understanding of the most important issues. In addition, these meetings led to the identification of areas where additional risk information and training are needed to ensure that a risk-informed, performance-based approach is consistently used in the high-level waste program. The documentation of the risk insights associated with the issue resolution agreements, the training, and the additional analyses are now the focus of the staff's effort.

NMSS Priority: High

Project Considerations: Completion of the review plan will enhance the ability of the staff and a potential license applicant to understand and comply with NRC's Part 63 requirements. The review plan will also be used to explain to external stakeholders how the NRC would review a potential license application.

NMSS has developed a communication plan for the high-level waste program (ADAMS Accession #ML003753322).

Resources Budgeted		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2002	2.9	875

Selected Major Milestones and Schedules			
Major Milestones	Original Target Date	Revised Date	Completion Date
Issue Final 10 CFR 63	September 2001		November 2001
Issue Yucca Mountain Review Plan, Revision 2	September 2001		March 2002
Public meetings on Yucca Mountain Review Plan	October 2001		May 2002
Provide staff preliminary sufficiency comments to Commission	October 2001		October 2001
Public release of preliminary sufficiency comments	November 2001		November 2001

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year															
Task	2001				2002				2003				2004		
	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3
Incorporate Risk Information into the High-Level Waste Regulatory Framework															
Prepare final 10 CFR Part 63															
Issue final 10 CFR Part 63															
Provide staff preliminary sufficiency comments to Commission															
Public release of preliminary sufficiency comments															
Issue Yucca Mountain Review Plan, Revision 2															
Public meeting on revised Yucca Mountain Review Plan															

Implementation Activity: Cross-cutting Risk Assessment of Spent Fuel Management

(Lead Organization: NMSS/RTG)

Primary Performance Goal: *Make the NRC activities and decisions more effective, efficient, and realistic. (EER)*

Strategy: *We will continue to improve the regulatory framework to increase our effectiveness, efficiency, and realism. (EER1)*

RTG is assessing the relative risks associated with spent fuel management during the different phases of the spent fuel life cycle: handling, storage, transportation and disposal. NRC regulations relevant to the spent fuel life cycle are 10 CFR Parts 20, 50, 63, 71, 72 and 73. Based on this risk assessment, the relative regulatory rigor applied to each phase of the spent fuel life cycle may be reviewed to determine if it is commensurate with the relative risks. This study should yield a better understanding of which phases of the spent fuel life cycle pose greater potential risks to workers and to members of the public. Quantifying the relative risks and identifying the more risk-significant aspects of spent fuel management can improve effectiveness and efficiency, and reduce unnecessary regulatory burden, by helping staff to focus resources on the more risk-significant activities of the spent fuel life cycle. Also, the results of the risk study may support modification of the regulatory framework or its implementation, in terms of licensing and inspection.

NMSS Priority: Medium

Project Considerations: The assessment of spent fuel risks is one of the cross-cutting activities identified in Phase 2.

Resources Budgeted*		
Fiscal Year	Staff Resources (FTE)	Fiscal Resources (K\$)
2002	0.2	90

*Note: These are the NMSS RTG budgeted resources that are allocated for this RTG activity only. NMSS RTG budgeted resources are also allocated to other activities, such as providing direct support to NMSS divisions for risk-related activities.

Selected Major Milestones and Schedules			
Major Milestones	Original Target Date	Revised Date	Completion Date
Initiate Contract	March 2002		March 2002
Complete Assessment	July 2002		

Implementation Activity Tasks, Interrelationships, and Schedules by Calendar Year																							
Task Name	2002																						2003
	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb				
Cross-cutting risk assessment of spent fuel																							
Initiate contract																							
Conduct assessment																							